

Midlothian Family Practice

5/23/2021

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Safety Data Sheet



Section 1: Identification

Product identifier

Product Name • **Acetic Acid Aluminum Acetate Otic Solution**

Product Code • AB06620; Core No. 066; NDC 24208-0615-77

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

Recommended use • Finished Pharmaceutical Product; For the treatment of superficial infections of the external auditory canal caused by organisms susceptible to the action of the antimicrobial.

Details of the supplier of the safety data sheet

Manufacturer • Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com

Telephone (General) • 1-800-553-5340

Emergency telephone number

Manufacturer • 1-800-535-5053 - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Skin Mild Irritation 3
Eye Mild Irritation 2B

Label elements

UN GHS

WARNING

Hazard statements • Causes mild skin irritation
Causes eye irritation

Precautionary statements

Prevention • Wash thoroughly after handling.
Use personal protective equipment as required.

Response • IF ON SKIN: Wash with plenty of soap and water.
If skin irritation or rash occurs: Get medical advice/attention.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses,

if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

- Storage/Disposal**
- Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.
 - Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Acetic acid	CAS:64-19-7 EINECS:200-580-7	2%	UN GHS: Skin Corr. 1A; Flam. Liq. 3
Aluminum sulfate	CAS:10043-01-3 EINECS:233-135-0	< 1%	UN GHS: NDA
Boric acid	CAS:10043-35-3 EINECS:233-139-2	< 0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1
Calcium carbonate	CAS:471-34-1 EINECS:207-439-9	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Sodium hydroxide	CAS:1310-73-2 EINECS:215-185-5	< 1%	UN GHS: Skin Corr. 1A
Water	CAS:7732-18-5 EINECS:231-791-2	> 90%	UN GHS: Classification criteria not met

Glacial Acetic Acid (CAS:64-19-7, EINECS:200-580-7) and/or Sodium Hydroxide (CAS# 1310-73-2, EINECS: 215-185-5) may be added to adjust the pH.

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention.

Skin

- Flush with fresh water if contact with skin or eyes. If skin irritation occurs: Get medical advice/attention.

Eye

- 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.

Ingestion

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed**Other information**

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Section 5: Fire-Fighting Measures**Extinguishing media**

Suitable Extinguishing Media • SMALL FIRES: Dry chemical, CO₂, water spray or regular foam.
LARGE FIRE: Water spray, fog or regular foam.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known.

Hazardous Combustion Products • None known.

Advice for firefighters

- Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

Section 6 - Accidental Release Measures**Personal precautions, protective equipment and emergency procedures**

Personal Precautions • No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures • Keep unauthorized personnel away. Ventilate closed spaces before entering. Stop leak if you can do it without risk.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures • Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Dispose of in accordance with Section 13.

Section 7 - Handling and Storage**Precautions for safe handling**

Handling • No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

Storage • Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from freezing.

Incompatible Materials or Ignition Sources

- None specified.

Section 8 - Exposure Controls/Personal Protection

Control parameters**Exposure Limits/Guidelines**

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Boric acid (10043-35-3)	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established	Not established
	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established	Not established
Calcium carbonate (471-34-1)	TWAs	Not established	10 mg/m3 TWAEV (total dust)	10 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable dust)	Not established
Sodium hydroxide (1310-73-2)	Ceilings	2 mg/m3 Ceiling	2 mg/m3 Ceiling	2 mg/m3 Ceiling	Not established
	TWAs	Not established	Not established	Not established	2 mg/m3 TWA
Acetic acid (64-19-7)	STELs	15 ppm STEL	15 ppm STEV; 37 mg/m3 STEV	15 ppm STEL; 37 mg/m3 STEL	Not established
	TWAs	10 ppm TWA	10 ppm TWAEV; 25 mg/m3 TWAEV	10 ppm TWA; 25 mg/m3 TWA	10 ppm TWA; 25 mg/m3 TWA

Exposure Control Notations**ACGIH**

- Boric acid (10043-35-3): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (listed under Borate compounds, inorganic))

Exposure controls**Engineering Measures/Controls**

- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment**Respiratory**

- In the event of a bulk spill, and where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. In the event of a spill, appropriate eye protection should be worn.

Hands

- Wear appropriate gloves.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

General Industrial Hygiene

- Wash thoroughly after handling.

Considerations**Environmental Exposure Controls**

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Color	Clear Colorless .
Odor	Vinegar-like	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	3.5 to 5
Specific Gravity/Relative Density	= 1.012	Water Solubility	Miscible
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Aluminum sulfate (< 1%)	10043-01-3	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 6207 mg/kg

Calcium carbonate (< 1%)	471-34-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • 6450 mg/kg
Boric acid (< 0.1%)	10043-35-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2500 mg/kg; <i>Behavioral:</i> Convulsions or effect on seizure threshold; Behavioral: Ataxia
Acetic acid (2%)	64-19-7	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 4960 mg/kg
Sodium hydroxide (< 1%)	1310-73-2	Acute Toxicity: Intraperitoneal-Mouse LD50 • 40 mg/kg

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Mild Irritation 3
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Mild Irritation 2B

Potential Health Effects

Inhalation

Acute (Immediate)

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- No data available.

Skin

Acute (Immediate)

- May cause mild irritation.

Chronic (Delayed)

- No data available.

Eye

Acute (Immediate)

- May cause irritation.

Chronic (Delayed)

- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects. Under normal conditions of use, no health effects are expected.

Ingestion

Acute (Immediate)

- Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.

Chronic (Delayed)

- No data available.

Carcinogenic Effects		
	CAS	NTP
Boric acid	10043-35-3	Evidence of Carcinogenicity

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available.

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	not regulated	NDA	NDA	NDA
TDG	NDA	not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	not regulated	NDA	NDA	NDA

Special precautions for user

- No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

- No data available

Other information

- DOT** • (49 CFR 172.101, .203) Acetic acid: DOT DESIGNATIONS; Listed chemical. Concentration required for hazardous material classification is a minimum of 10%. Product concentration claim for acetic acid is 2%.

Section 15 - Regulatory Information

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

SARA Hazard Classifications

- No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Acetic acid	64-19-7	Yes	Yes	Yes
Aluminum sulfate	10043-01-3	Yes	Yes	Yes
Boric acid	10043-35-3	Yes	Yes	Yes
Calcium carbonate	471-34-1	Yes	Yes	Yes
Sodium hydroxide	1310-73-2	Yes	Yes	Yes

Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Acetic acid	64-19-7	B3, E (including 10-80% [Available data does not allow a precise evaluation of the threshold concentration from which solutions meet the B3 criterion], >80%); D2B (3-10%)
• Aluminum sulfate	10043-01-3	D2B
• Sodium hydroxide	1310-73-2	E (including 0.04% in aqueous solution, 0.08%, 0.4% in aqueous solution, 2%, 2.5%, 4% in aqueous solution, 5%, 10%, 16%, 20%, 40%, 50% in aqueous solution, 8.7N)
• Boric acid	10043-35-3	D2A
• Calcium carbonate	471-34-1	Uncontrolled product according to WHMIS classification criteria
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Acetic acid	64-19-7	1 %
• Aluminum sulfate	10043-01-3	Not Listed
• Sodium hydroxide	1310-73-2	1 %
• Boric acid	10043-35-3	1 %
• Calcium carbonate	471-34-1	Not Listed
• Water	7732-18-5	Not Listed

Environment

Canada - CEPA - Priority Substances List

• Acetic acid	64-19-7	Not Listed
• Aluminum sulfate	10043-01-3	Priority Substance List 2 (substance not considered toxic)
• Sodium hydroxide	1310-73-2	Not Listed
• Boric acid	10043-35-3	Not Listed
• Calcium carbonate	471-34-1	Not Listed
• Water	7732-18-5	Not Listed

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• Acetic acid	64-19-7	R10 C; R35
• Aluminum sulfate	10043-01-3	Not Listed
• Sodium hydroxide	1310-73-2	C; R35
• Boric acid	10043-35-3	Repr.Cat.2; R60-61
• Calcium carbonate	471-34-1	Not Listed

• Water	7732-18-5	Not Listed
EU - CLP (1272/2008) - Annex VI - Table 3.2 - Concentration Limits		
• Acetic acid	64-19-7	10%≤C<25%: Xi; R:36/38 90%≤C: C; R:35 25% ≤C<90%: C; R:34
• Aluminum sulfate	10043-01-3	Not Listed
• Sodium hydroxide	1310-73-2	5%≤C: C; R:35 2%≤C<5%: C; R:34 0.5%≤C<2%: Xi; R:36/38
• Boric acid	10043-35-3	5.5%≤C: Repr.Cat.2; R:60-61
• Calcium carbonate	471-34-1	Not Listed
• Water	7732-18-5	Not Listed
EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling		
• Acetic acid	64-19-7	C R:10-35 S:(1/2)-23-26-45
• Aluminum sulfate	10043-01-3	Not Listed
• Sodium hydroxide	1310-73-2	C R:35 S:(1/2)-26-37/39-45
• Boric acid	10043-35-3	T R:60-61 S:53-45
• Calcium carbonate	471-34-1	Not Listed
• Water	7732-18-5	Not Listed
EU - CLP (1272/2008) - Annex VI - Table 3.2 - Notes - Substances and Preparations		
• Acetic acid	64-19-7	B
• Aluminum sulfate	10043-01-3	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Boric acid	10043-35-3	Not Listed
• Calcium carbonate	471-34-1	Not Listed
• Water	7732-18-5	Not Listed
EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases		
• Acetic acid	64-19-7	S:(1/2)-23-26-45
• Aluminum sulfate	10043-01-3	Not Listed
• Sodium hydroxide	1310-73-2	S:(1/2)-26-37/39-45
• Boric acid	10043-35-3	S:53-45
• Calcium carbonate	471-34-1	Not Listed
• Water	7732-18-5	Not Listed

United States

Environment

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

• Acetic acid	64-19-7	5000 lb final RQ; 2270 kg final RQ
• Aluminum sulfate	10043-01-3	5000 lb final RQ; 2270 kg final RQ
• Sodium hydroxide	1310-73-2	1000 lb final RQ; 454 kg final RQ
• Boric acid	10043-35-3	Not Listed
• Calcium carbonate	471-34-1	Not Listed
• Water	7732-18-5	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Acetic acid	64-19-7	Not Listed
• Aluminum sulfate	10043-01-3	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Boric acid	10043-35-3	Not Listed
• Calcium carbonate	471-34-1	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Acetic acid	64-19-7	Not Listed
• Aluminum sulfate	10043-01-3	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Boric acid	10043-35-3	Not Listed
• Calcium carbonate	471-34-1	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Acetic acid	64-19-7	Not Listed
• Aluminum sulfate	10043-01-3	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Boric acid	10043-35-3	Not Listed
• Calcium carbonate	471-34-1	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Acetic acid	64-19-7	Not Listed
• Aluminum sulfate	10043-01-3	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Boric acid	10043-35-3	Not Listed
• Calcium carbonate	471-34-1	Not Listed
• Water	7732-18-5	Not Listed

Section 16 - Other Information

Last Revision Date

- 15/May/2015

Preparation Date

- 14/May/2015

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SDS: Acetic Acid Otic Solution, USP

SAFETY DATA SHEET

1. Identification

Product Identifier: Acetic Acid Otic Solution, USP

Synonyms: Methanecarboxylic acid * Ethanoic acid

National Drug Code (NDC): 50383-889-15

Recommended Use: Pharmaceutical.

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 classifiable.

Health Hazards: Not classifiable.

Symbol(s): None.

Signal Word: None.

Hazard Statement(s): None.

Precautionary Statement(s): None.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Acetic Acid	64-19-7	Methanecarboxylic acid * Ethanoic acid	CH ₃ COOH	60.05	2%
Propylene Glycol Diacetate	623-84-7	1,2-Propanediol	C ₇ H ₁₂ O ₄	160.16	3%
Benzethonium Chloride	121-54-0	Benzethonium Chloride	C ₂₇ H ₄₂ ClNO ₂	448.15	0.02%
Sodium Acetate	127-09-3	Acetic acid, sodium salt	C ₂ H ₃ NaO ₂	82.04	0.015%



SDS: Acetic Acid Otic Solution, USP

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:	Solution is not considered hazardous under normal conditions.
Medical Conditions Aggravated by Exposure:	As with all pharmaceutical, hypersensitivity is possible.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:	Use standard firefighting procedures depending on the source of the surrounding fire.
Unsuitable Extinguishing Media:	Not determined.



SDS: Acetic Acid Otic Solution, USP

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:	Not determined.
Other Specific Hazards:	Not determined.
Special Protective Equipment/ 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:	Pick up in the most efficient manner. Soak up with sawdust, sand, oil dry or other absorbent material.
Environmental Precautions:	No data available.
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:	Keep container tightly closed. Store between 68°F – 77°F. Store according to label and/or product insert information.
Specific End Use:	Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Acetic Acid	OSHA PEL: 25 mg/m ³ OSHA PEL: 10 ppm NIOSH REL: 25 mg/m ³ NIOSH STEL: 10 ppm; 37 mg/m ³ ; 15 ppm ACGIH TLV: 15 ppm STEL ACGIH TLV: 15 ppm TWA
Propylene Glycol Diacetate	WEEL: 25 mg/m ³ TWA (Aerosol)
Benzethonium Chloride	Not established.
Sodium Acetate	Not established.

Engineering Controls:	Not required for the normal use of this product. Engineering controls should be used as the primary means to control exposures.



SDS: Acetic Acid Otic Solution, USP

Respiratory Protection:	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:	Safety glasses with side shields are recommended. 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:	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.

9. Physical and Chemical Properties

Physical State/Color:	Clear, colorless liquid, free from sediment and foreign matter.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	Nonflammable.
Evaporation Rate:	Same as water.
Flammability (solid, gas):	No data available.
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):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.
Specific Gravity:	1.03410.



SDS: Acetic Acid Otic Solution, USP

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions. Avoid sources of ignition.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Strong oxidizer. Avoid excessive heat.
Hazardous Decomposition Products:	Does not undergo explosive decomposition.
Hazardous Polymerization:	Will not occur.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	No data available.
Ingestion:	Harmful if swallowed.
Skin Contact:	No data available.
Eye Contact:	May cause irritation of the eyes by prolonged skin contact.
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 – Oral:	No data available.
Acute Toxicity – Dermal:	No data available.
Acute Toxicity – Inhalation:	No data available.
Corrosivity:	No data available.
Dermal Irritation:	No data available.
Eye Irritation:	No data available.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	No data available.
Reproductive Effects:	No data available.
Carcinogenicity:	No data available.



SDS: Acetic Acid Otic Solution, USP

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.

Mutagenicity: No data available.

Aspiration Hazard: No data available.

12. Ecological Information

Ecotoxicity

Aquatic: No data available.

Terrestrial: No data available.

Persistence and Degradability: No data available.

Bioaccumulative Potential: No data available.

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

UN Number: Not applicable.

UN Proper Shipping Name: Not applicable.

Transport Hazard Class(es): Not applicable.

Packing Group: Not applicable.

Department of Transportation: Not regulated as a hazardous material.

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

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

15. Regulatory Information

US Federal Regulations:

**Toxic Substance Control Act
(TSCA):** Not listed.

**CERCLA Hazardous Substance
and Reportable Quantity:** Not listed.

SARA 313: Not listed.

SARA 302: Not listed.



SDS: Acetic Acid Otic Solution, USP

State Regulations

California Proposition 65: Not listed.

16. Other Information

NFPA Rating:

Health:	1
Flammability:	0
Reactivity:	0

Revision Date: 05/30/2015

Revision Number:

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SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Contact information

General



Par Sterile Products
870 Parkdale Road, Rochester, M.I. 48307
T: +1 (800) 828-9393
F: +1 (201) 829-9222
E-mail: drugsafety@parpharm.com

Emergency telephone number

Chemtrec (24-hour availability):
+1 (800) 424-9300 (USA and Canada)
+1 (703) 527-3887 (International; collect calls accepted)

Product identifier	Adrenalin® (epinephrine for Injection, USP); Adrenalin® Chloride Nasal Solution (epinephrine nasal solution, USP)
Synonyms	Epinephrine chloride solution; For epinephrine: 4-[1-hydroxy-2-(methylamino)ethyl]1,2 benzenediol
Trade names	Adrenalin®
Chemical family	Mixture - contains benzenediol derivative
Relevant identified uses of the substance or mixture and uses advised against	Bulk formulated pharmaceutical mixture/Formulated pharmaceutical product packaged in final form for patient use; indicated for the emergency treatment of severe acute allergic reactions, asthma, and chronic pulmonary disease.
Note	This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product. This SDS will be revisited if more data become available.
Issue Date	1 May 2015

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture	Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada. Please consult the prescribing/packaging information. The classification and labeling listed below is for bulk Epinephrine Solution.
Regulation (EC) 1272/2008 [GHS]	Not classified
Directive 67/548/EEC or 1999/45/EC	Not classified
Label elements	
CLP/GHS hazard pictogram	None required
CLP/GHS signal word	None required
CLP/GHS hazard statements	None required
CLP/GHS precautionary statements	None required
EU symbol/indication of danger	None required
Risk (R) Phrase(s)	None required
Safety Advice	None required
Other hazards	Epinephrine (<i>i.e.</i> , adrenaline) is an endogenous neurotransmitter hormone and its primary effects are vasoconstriction, cardiac stimulation, and smooth muscle relaxation. The most common adverse effects reported with therapeutic use include transient/moderate anxiety, feelings of over stimulation, restlessness, headache, tremor, weakness, shakiness, dizziness, sweating, increased heart rate, palpitations, paleness, nausea, vomiting, and difficulty breathing. Other symptoms, such as high blood pressure, cardiac arrhythmias, and cerebral bleeding, have occurred. As epinephrine can cross the placenta, it may adversely affect the fetus (<i>e.g.</i> , reduce fetal oxygen levels due to constriction of blood vessels).
US Signal word	None required
US Hazard overview	None required
Note	This mixture does not meet criteria for classification according to directive 1999/45/EC and Regulation EC No 1272/2008 (EU CLP). Nevertheless, it should be regarded as dangerous/hazardous because it contains a pharmacologically active substance and should be handled with care. The GHS classifications are based on Regulation (EC) 1272/2008. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 1999/45/EC.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>EU Classification</u>	<u>GHS Classification</u>
Chlorbutanol	57-15-8	200-317-6	≤ 0.5%	Harmful - Xn: R22	ATO4: H302
Epinephrine	51-43-4	200-098-7	≤ 0.1 %	Toxic - T: R23/ 24/25, R48/23/24/ 25, R61, R62	ATO2: H300; ATD2: H310; ATI2: H330; STOT-R1: H372; RT1B: H360Df

Note The ingredient(s) listed above are considered dangerous/hazardous. The remaining components are non-dangerous/not hazardous and/or present at amounts below reportable limits. See Section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.

SECTION 4 - FIRST AID MEASURES

**Description of first aid
measures**
**Immediate Medical
Attention Needed**

Yes

Eye Contact

If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

Skin Contact

Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

Inhalation

Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

Ingestion

Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

**Protection of first aid
responders**

See Section 8 for Exposure Controls/Personal Protection recommendations.

**Most important
symptoms and effects,
both acute and delayed**

See Sections 2 and 11.

SECTION 4 - FIRST AID MEASURES ...continued

Indication of immediate medical attention and special treatment needed, if necessary	Contains epinephrine, a potent vasoconstricting-agent. Medical conditions aggravated by exposure: cardiovascular diseases, hypertension, and hypersensitivity. Rapidly acting vasodilators can counteract the the marked pressor effects of epinephrine. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package or prescribing information for potential drug interactions.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen and sulfur, nitric and sulfuric acid, hydrochloric acid, and other nitrogen-, sulfur-, and/or chlorine-containing compounds.
Flammability/Explosivity	No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.
Advice for firefighters	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe mist/spray.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	If vials are crushed or broken, DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9).
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	If vials are opened, crushed or broken, follow recommendations for handling bulk formulated pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling.
Conditions for safe storage including any incompatibilities	Store at controlled room temperature (20-25°C) away from incompatible materials. Protect from light. Keep container upright. Discard unused portion.
Specific end use(s)	No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Note Dispose of broken vials in a sharps container.

**Control Parameters/
Occupational Exposure
Limit Values**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Chlorbutanol	--	--	--
Epinephrine	--	--	--

Exposure/Engineering controls None required for normal handling of packaged product. If handling bulk product or if vials are opened/crushed/broken: Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Open handling must not be performed when handling potent substances, or substances of unknown toxicity. Material should be handled inside a closed process, ventilated enclosure, isolator or device of equivalent or better control that is suitable for dusts and/or aerosols.

Respiratory protection None required for normal handling of packaged product. If handling bulk product or if vials are opened/crushed/broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine handling tasks, an approved and properly worn powered air-purifying respirator equipped with appropriate HEPA filters or combination filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where air purifying respirators may not provide adequate protection.

Hand protection None required for normal handling of packaged product. Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered.

Skin protection Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

Eye/face protection Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued

Environmental Exposure Controls	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
Other protective measures	Wash hands in the event of contact with this mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Liquid in vials
Color	Colorless
Odor	Odorless
Odor threshold	No information identified.
pH	3.3-4.2
Melting point/freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
Evaporation rate	No information identified.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified
Vapor density	No information identified.
Relative density	No information identified.
Water solubility	Soluble in water
Solvent solubility	No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

Partition coefficient (<i>n</i>-octanol/water)	No information identified.
Auto-ignition temperature	No information identified.
Decomposition temperature	No information identified.
Viscosity	No information identified.
Explosive properties	No information identified.
Oxidizing properties	No information identified.
Other information	
Molecular weight	Not applicable (Mixture)
Molecular formula	Not applicable (Mixture)

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	No information identified.
Possibility of hazardous reactions	No information identified.
Conditions to avoid	Avoid extreme temperatures.
Incompatible materials	No information identified.
Hazardous decomposition products	No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Note	No toxicology data for the product/mixture were identified. The following data describe the active ingredient or other individual ingredients, where applicable.
Information on toxicological effects	
Route of entry	May be absorbed by inhalation, skin contact and ingestion.

SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Chlorbutanol	LD ₅₀	Oral	Rat	510 mg/kg
	LD ₅₀	Oral	Mouse	150 mg/kg
Epinephrine	LD ₅₀	Intravenous	Rat	150 µg/kg*
	LD ₅₀	Intravenous	Mouse	217 µg/kg
	LD ₅₀	Intravenous	Dog	100 µg/kg
	LD ₅₀	Dermal	Rat	62 mg/kg
	LD _{LO}	Oral	Mouse	50 mg/kg
	LD _{LO}	Oral	Rat	30 mg/kg

Additional acute toxicity information

*To err on the side of caution (due to the high potency of this substance), it is assumed that toxicity *via* inhalation may be comparable to the intravenous route.

Irritation/Corrosion

No data available.

Sensitization

No data available.

STOT-single exposure

No data available.

STOT-repeated exposure/Repeat-dose toxicity

In 13-week inhalation studies, increased respiratory rate, changes in respiratory epithelium, and increased heart/adrenal gland weight were observed in rats and mice exposed to 40 mg/m³ epinephrine (duration not specified). Additionally, degenerative lesions of the laryngeal muscle were seen in rats exposed to concentrations ≥20 mg/m³. In mice, inflammation of the glandular stomach and uterine atrophy were observed at concentrations ≥10 and 40 mg/m³, respectively.

Reproductive toxicity

In hamsters, epinephrine caused a decrease in reproductive success at 500 µg/kg (route of administration not specified). In mice, epinephrine decreased sexual receptivity in female mice at subcutaneous (SC) doses of 40 µg (~1.6 mg/kg), but implantation success was not affected.

Developmental toxicity

Adverse developmental effects have been reported in rabbits, mice, and hamsters at SC doses as low as 1.2, 1 and 0.5 mg/kg, respectively. Uterine vasoconstriction and impaired fetal gas exchange were observed in pregnant monkeys treated with intravenous (IV) doses of 0.5-20 µg/kg/min for 1 to 18 minutes. Fetal asphyxia was observed after epinephrine administration to pregnant monkeys at doses similar to those used in humans.

Genotoxicity

Epinephrine was negative in the Ames bacterial mutagenicity assay and an *in vivo* micronucleus assay (species not specified). Although both negative and equivocal effects were observed in a chromosomal aberration assay with Chinese hamster ovary cells in the presence and absence of metabolic activation, respectively, the overall weight of evidence suggests a low genotoxicity potential.

Carcinogenicity

Epinephrine was not carcinogenic in rats and mice exposed by inhalation to concentrations up to 5 and 3 mg/m³, respectively. None of the components present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

Aspiration hazard

No data available.

SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

Human health data See Section 2 - "Other hazards"

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Chlorbutanol	LC ₅₀ (time not specified)	<i>Pimephales promelas</i> (fathead minnow)	130-141 mg/L
Epinephrine	--	--	--

Persistence and Degradability

No data identified.

Bioaccumulative potential

No data identified.

Mobility in soil

No data identified.

Results of PBT and vPvB assessment

Not performed.

Other adverse effects

No data identified.

Note

The environmental characteristics of this mixture have not been fully investigated. The above data are for the active ingredient and/or any other ingredient(s) where applicable. Releases to the environment should be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods

Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

SECTION 14 - TRANSPORT INFORMATION

Transport

Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.

UN number

None assigned.

UN proper shipping name

None assigned.

SECTION 14 - TRANSPORT INFORMATION ...continued

Transport hazard classes and packing group	None assigned.
Environmental hazards	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
Special precautions for users	Avoid release to the environment.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local/regional authorities for more information.
Chemical safety assessment	Not conducted.
OSHA Hazardous	No
WHMIS classification	Not required. Drugs are not subject to WHMIS. This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.
TSCA status	Drugs are exempt from TSCA.
SARA section 313	Not listed.
California proposition 65	Not listed.
Additional information	No other information identified.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications	Xn - Harmful. T - Toxic. R22 - Harmful if swallowed. R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed. R48/23/24/25 - Toxic: Danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed. R61 - May cause harm to the unborn child. R62 - Possible risk of impaired fertility.

SECTION 16 - OTHER INFORMATION ...continued

Full text of H phrases, P phrases and GHS classification	ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. ATO2 - Acute Toxicity (Oral) Category 2. H300 - Fatal if swallowed. ATD2 - Acute Toxicity (Dermal) Category 2. H310 - Fatal in contact with skin. STOT-R1 - Specific Target Organ Toxicity Following Repeat Exposure Category 1. H372 - Causes damage to the cardiovascular system through prolonged or repeated exposure. RT1B - Reproductive toxicity Category 1B. H360Df - May damage the unborn child. Suspected of damaging fertility.
Sources of data	Information from published literature and internal company data.
Abbreviations	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
Revisions	Updated contact information and product identifier in Section 1.
Disclaimer	The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to

SECTION 16 - OTHER INFORMATION ...continued

Disclaimer ...continued

the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

Safety Data Sheet



Section 1: Identification

Product identifier

Product Name • **Advanced Eye Relief™ Eye Wash**

Product Code • 620252; FCP-4822

Product Description • Eye wash.

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

Recommended use • Gently cleanses and refreshes the eye to help relieve irritation, stinging and discomfort by removing loose foreign material, air pollutants (pollen, ragweed), dust or chlorinated water.

Restrictions on use • Use in accordance with product literature.

Details of the supplier of the safety data sheet

Manufacturer • Bausch & Lomb, Inc
1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com

Telephone (General) • 1-800-553-5340

Emergency telephone number

Manufacturer • 1-800-535-5053 - Infotrac

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Classification criteria not met

Label elements

UN GHS

Precautionary statements

Storage/Disposal • Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

Other hazards

UN GHS • No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance.

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Boric acid	CAS:10043-35-3 EINECS:233-139-2	< 1.3%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1
Sodium borate	CAS:1303-96-4	< 1.3%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 2
Edetate disodium	CAS:6381-92-6	0.025%	UN GHS: not classified
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	< 1.3%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Purified water	CAS:7732-18-5 EINECS:231-791-2	> 95%	UN GHS: not classified
Sorbic acid	CAS:110-44-1 EINECS:203-768-7	0.1%	UN GHS: not classified

Hydrochloric Acid (CAS:7647-01-0, EINECS:231-595-7) and/or Sodium Hydroxide (CAS# 1310-73-2, EINECS: 215-185-5) may be added to adjust the pH.

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

Eye

- No specific treatment is necessary since this material is not irritating to the eye.

Ingestion

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards

- None known - product is not flammable or combustible.

Hazardous Combustion Products

- No data available

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures**Personal precautions, protective equipment and emergency procedures****Personal Precautions**

- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Refer to Section 8.

Emergency Procedures

- No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available

Methods and material for containment and cleaning up**Containment/Clean-up Measures**

- Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

Section 7 - Handling and Storage**Precautions for safe handling****Handling**

- No special handling is required. Refer to Section 8. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities**Storage**

- Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection**Control parameters****Exposure Limits/Guidelines**

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines				
	Result	ACGIH	Canada Quebec	NIOSH
Sodium borate (1303-96-4)	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)	5 mg/m3 TWAEV	5 mg/m3 TWA
	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established
Boric acid (10043-35-3)	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established
		2 mg/m3 TWA (inhalable fraction,		

	TWAs listed under Borate compounds, inorganic)	Not established	Not established

Exposure controls

Engineering Measures/Controls

- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory

- No respiratory protection required during normal handling.

Eye/Face

- No eye protection is required during normal handling.

Hands

- Gloves are not required under normal handling conditions.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Color	Clear Colorless to slightly yellow.
Odor	No odor.	Odor Threshold	Not relevant
General Properties			
Boiling Point	Not relevant	Melting Point	Not relevant
Decomposition Temperature	Not relevant	pH	7.1 to 7.7
Specific Gravity/Relative Density	= 1.007	Water Solubility	Not relevant
Viscosity	Not relevant		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	Not relevant		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reactions known.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information

Information on toxicological effects

Other Material Information • Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Components		
Boric acid (< 1.3%)	10043-35-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2660 mg/kg
Sodium borate (< 1.3%)	1303-96-4	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2660 mg/kg
Sodium chloride (< 1.3%)	7647-14-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3000 mg/kg
Sorbic acid (0.1%)	110-44-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • 7360 mg/kg

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met

Potential Health Effects

Inhalation

Acute (Immediate)

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- Under normal conditions of use, no health effects are expected.

Skin

Acute (Immediate)

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- Under normal conditions of use, no health effects are expected.

Eye

Acute (Immediate)

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- Under normal conditions of use, no health effects are expected.

Ingestion

Acute (Immediate)

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- Under normal conditions of use, no health effects are expected.

Other**Acute (Immediate)**

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- Under normal conditions of use, no health effects are expected.

Carcinogenic Effects		
	CAS	NTP
Boric acid	10043-35-3	Evidence of Carcinogenicity

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods**Product waste**

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	NDA	NDA	NDA	NDA
ADN	NDA	NDA	NDA	NDA	NDA
ADR/RID	NDA	NDA	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

Special precautions for user

- No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

- No data available

Section 15 - Regulatory Information

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

SARA Hazard Classifications • No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Edetate disodium	6381-92-6	Yes	No	No
Sodium borate	1303-96-4	Yes	No	Yes
Boric acid	10043-35-3	Yes	Yes	Yes
Purified water	7732-18-5	Yes	Yes	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Sodium borate	1303-96-4	D2B
• Edetate disodium	6381-92-6	Uncontrolled product according to WHMIS classification criteria
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Boric acid	10043-35-3	D2A
• Purified water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Sodium borate	1303-96-4	1 %
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	1 %
• Purified water	7732-18-5	Not Listed

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• Sodium borate	1303-96-4	Repr.Cat.2; R60-61
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Repr.Cat.2; R60-61
• Purified water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Concentration Limits

• Sodium borate	1303-96-4	8.5%≤C: Repr.Cat.2; R:60-61
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	5.5%≤C: Repr.Cat.2; R:60-61
• Purified water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Sodium borate	1303-96-4	T R:60-61 S:53-45
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	T R:60-61 S:53-45
• Purified water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Notes - Substances and Preparations

• Sodium borate	1303-96-4	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Purified water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Sodium borate	1303-96-4	S:53-45
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	S:53-45
• Purified water	7732-18-5	Not Listed

United Kingdom**Environment****United Kingdom - List of Chemicals of Concern**

• Sodium borate	1303-96-4	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Purified water	7732-18-5	Not Listed

United States**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Sodium borate	1303-96-4	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Purified water	7732-18-5	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Sodium borate	1303-96-4	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Purified water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Sodium borate	1303-96-4	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed

• Purified water	7732-18-5	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
• Sodium borate	1303-96-4	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Purified water	7732-18-5	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
• Sodium borate	1303-96-4	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Purified water	7732-18-5	Not Listed

Section 16 - Other Information

Last Revision Date

- 10/February/2015

Preparation Date

- 10/February/2015

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Revision date: 02-01-2017

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Nephron Pharmaceuticals Corporation
4500 12th Street Extension
West Columbia, SC 29172-3025

(803) 569-2800
(800) 443-4313 (24 hour contact)

PRODUCT NAME: Albuterol Sulfate Inhalation Solution, 0.083%*
*potency expressed as albuterol
COMMON NAME: albuterol sulfate
CHEMICAL NAME: α^1 -[tert-butylamino)-methyl]-4-hydroxy-m-xylene- α - α' -diol sulfate (2:1) (salt)
INN: Salbutamol
SUBSTANCE CLASS: Benzyl alcohol derivative: bronchodilator
INTENDED USE: Pharmaceutical product used as bronchodilator

SECTION 2: HAZARD(S) IDENTIFICATION

The following adverse effects have been reported with medicinal use of Albuterol Sulfate Inhalation Solution, 0.083% and may accompany unintentional exposure in sufficient dose: fine muscle tremors, muscle cramps, nausea/vomiting, headache, dizziness, nervousness, heartburn, and rapid pulse, palpitations, and increased blood pressure. Extremely rapid heartbeat, seizures, low serum potassium levels, and worsening of the symptoms of pre-existent cardiovascular (heart and blood vessel) conditions and diabetes are possible. Hypersensitivity reactions such as hives, skin rash, constriction of the air passages in the lungs, and swelling involving the skin and mucous membranes have been reported.
(See Section 11, "Toxicological Information")

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

NAME: Albuterol Sulfate
CAS#: 51022-70-9
% w/v 0.1% Albuterol Sulfate (which is equivalent to 0.083% albuterol)
GW Limits 0.010 mg/m³
Other Limits: Not Established
NAME: Water for Injection
CAS# 7732-18-5

SECTION 4: FIRST AID MEASURES

If In Eyes: Flush with large amounts of cool water for at least 15 minutes. Obtain medical attention.
If On Skin: Wash affected areas with soap and water after removing contaminated clothing. Obtain medical attention if contamination is significant and/or a skin reaction is evident.
If Inhaled: If not breathing, give artificial respiration or CPR. If breathing is difficult, give oxygen. Obtain medical attention and remove to fresh air.
If Ingested: If awake and able to swallow, rinse mouth with water. Never give anything by mouth if unconscious or having convulsions. Obtain medical attention.

SECTION 5: FIRE FIGHTING MEASURES

FLASH POINT/TEST METHOD:	Unknown.
LEL/UEL:	Unknown.
SPECIAL PROPERTIES RELATED TO FIRE HAZARD:	None.
STORAGE OR HANDLING CONDITIONS TO BE AVOIDED:	Extreme Heat.
EXTINGUISHING MEDIA:	Water Spray, Multipurpose Dry Chemical.
FIRE-FIGHTING PROCEDURES:	Wear full protective clothing and use self-contained breathing apparatus (SCBA).

SECTION 6: ACCIDENTAL RELEASE MEASURES

SPILL RESPONSE PROCEDURES (Liquid, Solid, Gas/Vapor):

Protective equipment may be necessary for spills, (See Section 8, "Exposure Controls / Personal Protection" for guidance).

For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, collect spillage by carefully sweeping or wiping and place in a labeled, sealed container for disposal. Wash spill area (floor or other contact surfaces) with a suitable cleaning solvent, like ethanol.

SECTION 7: HANDLING AND STORAGE

HANDLING:	Avoid contact with eyes, skin, and clothing.
STORAGE:	Store between 36° and 77° F. Discard if solution becomes discolored.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS: No special ventilation required.

PERSONAL PROTECTION:

Respiratory:	Not required under normal conditions of therapeutic use. See Section 5 "Fire-Fighting Measures" for respiratory protection in the event of a fire.
Eye:	Not required for recommended dosage and administration. Workers should wear adequate eye protection if splash hazard exists.
Clothing:	Adequate protective clothing should be worn to prevent occupational skin contact.
Gloves:	When routine handling or spill cleanup may result in skin contact, impermeable (e.g., latex) gloves should be worn.
Work Practices:	Special care should be taken to ensure that contaminated clothing, equipment and work surfaces are properly cleaned after use. Wash hands and other areas of skin contact thoroughly after handling this material. Contaminated clothing should be cleaned or disposed of.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AND ODOR:	Clear, colorless to light yellow; odorless.
PHYSICAL STATE:	Liquid.
MELTING POINT:	Not determined.
BOILING POINT:	Not determined.
SOLUBILITY/MISCIBILITY (%w/v):	Not determined. The solubility of albuterol sulfate, the active ingredient, is 25% w/v in water. Albuterol sulfate is slightly soluble in ethanol, chloroform and ether.

SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY:	Stable.
CONDITIONS TO AVOID:	Not determined.
INCOMPATIBILITY WITH OTHER MATERIALS:	Not determined. No known incompatibilities have been identified for albuterol sulfate, the active ingredient in Albuterol Sulfate Inhalation Solution, 0.083%.
HAZARDOUS DECOMPOSITION PRODUCTS:	Hazardous decomposition products have not been determined. Thermal decomposition products of albuterol sulfate, the active ingredient, include toxic and/or corrosive oxides of nitrogen.

SECTION 11: TOXICOLOGICAL INFORMATION

THE RISK OF HEALTH HAZARDS MAY BE REDUCED WHEN ALBUTEROL SULFATE INHALATION SOLUTION, 0.042% and 0.021 % IS HANDLED IN UNIT DOSAGE FORM.

PHARMACOLOGICAL ACTIVITY:	The active component is albuterol sulfate. Albuterol sulfate is a β_2 -adrenergic bronchodilator used for the therapeutic effect of bronchial smooth muscle relaxation. This product is used for the prevention and relief of bronchospasm in patients with reversible obstructive airway disease (asthma) and for acute attacks of bronchospasm.
OCCUPATIONAL EXPOSURE LIMITS:	For albuterol sulfate, the estimated safe working level is an eight-hour time-weighted average (TWA) of 0.010mg/m ³ or 10 mcg/m ³ .
ACUTE TOXICITY:	Overexposure to albuterol sulfate in the occupational setting may result in the same adverse effects which have been observed when albuterol sulfate is used medically. (See "Repeat Dose Toxicity" and "Clinical Safety", below). Albuterol sulfate may be absorbed following ingestion, inhalation, and to a limited extent, through the skin.
REPEAT DOSE TOXICITY:	When used medically the following adverse effects have been reported: fine muscle tremors (especially the hands), muscle cramps, nausea or vomiting, headache, vertigo (dizziness), nervousness, heartburn, and rapid pulse, palpitations, and increased blood pressure. Hypersensitivity reactions (ranging from mild to life-threatening), such as urticaria (hives), skin rash, bronchospasm (constriction of the air passages in the lungs), and angioedema (swelling involving the skin and mucous membranes) have rarely occurred. In addition, albuterol sulfate may cause significant changes in blood pressure, extremely rapid heartbeat, seizures, low potassium levels, and may exacerbate the symptoms of pre-existent cardiovascular (heart and blood vessel) conditions and diabetes.
IRRITATION:	Albuterol sulfate causes eye irritation; avoid contact with the eyes. Albuterol sulfate is irritating to the nose and throat.
SENSITIZATION:	Rarely, exposure to albuterol sulfate can cause an allergic rash with redness and itching of the skin. Exposure by inhalation can cause an allergic rash, difficulty breathing and swelling of the face and airways.
REPRODUCTIVE EFFECTS:	Albuterol sulfate causes birth defects in mice. Rare reports of cleft palate and limb defects have been received in offspring of patients being treated with albuterol sulfate. There are no adequate and well-controlled studies of the effects of albuterol sulfate in pregnant women. Albuterol sulfate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. For recommended dosage and administration, Albuterol Sulfate Inhalation Solution, 0.083% is classified as "Pregnancy Category C". It is not known whether this drug is excreted in human milk. A decision should be made whether

to discontinue nursing or to discontinue using the drug, taking into account the importance of the drug to the mother. Precautions should be taken to limit the exposure to Albuterol Sulfate Inhalation Solution, 0.083% while pregnant or nursing; medical evaluation of exposure and attention to compliance with standard operating procedures and/or other workplace health and safety directives is advised.

GENOTOXICITY:

There is no evidence that albuterol sulfate is mutagenic (causing changes in genetic material) or impairs fertility in standard tests.

CARCINOGENICITY:

Albuterol sulfate was not carcinogenic in standard tests with mice and hamsters. Albuterol sulfate causes benign tumors to rats treated daily for 2 years with doses which are much greater than the recommended maximum dose for human medical use. The relevance of this finding to humans is not known.

CLINICAL SAFETY:

Individuals known to be hypersensitive to β -adrenergic agents like albuterol sulfate should not be exposed. Persons with cardiovascular disorders (including coronary artery disease, heart rhythm abnormalities and high blood pressure), seizure disorders (epilepsy) hyperthyroidism, or diabetes may experience worsening of symptoms from occupational exposure. Also, persons using Albuterol Sulfate Inhalation Solution, 0.083 % or other medications in the same therapeutic class (β_2 -adrenergic receptor agonists), or taking monoamine oxidase inhibitors or tricyclic antidepressants, may have increased sensitivity to the effects of albuterol sulfate in the occupational setting.

SECTION 12: ECOLOGICAL INFORMATION**ENVIRONMENTAL FATE:**

Albuterol compartmentalizes into the aquatic environment.

ENVIRONMENTAL EFFECTS:

Albuterol is not readily biodegradable in water or soil and is unlikely to bioaccumulate. It has toxicity to receptors in the aqueous environment at levels greater than 83.2 mg/L.

STUDY NAME	RESULTS
Water Solubility	24.5% w/v at pH 7
Hydrolysis Rate	Does not hydrolyze
Vapor Pressure	2×10^{-5} Pascals at 25° C
Dissociation Constant	pKa = 9.14
n-Octanol/Water Partition Coefficient	1.7×10^{-3} at pH 7
UV/Visible Spectrum	15300 at 225 nm water 1500 at 225 nm in HCl 2400 at 244 nm in NaOH
Aerobic Biodegradation (soil)	Partial biodegradation in soil 38.7% maximum in clay loam
Aerobic Biodegradation (water)	Not readily biodegradable
Soil Adsorption/Desorption	Low adsorption <25%
Activated sludge respiration inhibition test	>830 mg at 3 hours
Five day bacterial inhibition	No effect at 18.5 mg/L
Acute toxicity to Daphnia	LC ₅₀ = 243 mg at 48 hours No effect 83.2 mg/L

ENVIRONMENTAL TEST RESULTS:**SECTION 13: DISPOSAL CONSIDERATIONS****ROUTINE**

Unused product should be disposed of at an approved facility in accordance with federal, state and local regulations.

Albuterol Sulfate Inhalation Solution, 0.083%

Effective Date: 02-01-2017

ACCIDENTAL RELEASE: Clean up spills immediately, observing precautions in Section 8 - "Exposure Controls / Personal Protection".
Remove or decontaminate all residues in accordance with federal, state and local regulations.

SECTION 14: TRANSPORT INFORMATION

Component 1 or Formulation 1: Albuterol Sulfate Inhalation Solution, 0.083%

US Department of Transportation

Proper Shipping Name: Pharmaceutical for Interstate Commerce

IATA/ICAO

Proper Shipping Name: Not Regulated

IMDG

Proper Shipping Name: Not Regulated

RQ: None Marine Pollutant: No

SECTION 15: REGULATORY INFORMATION

EC PACKAGING AND LABELING FOR SUPPLY: Not applicable.

OTHER LEGISLATION: Not regulated.

SECTION 16: OTHER INFORMATION

REVISION DATE: 07-22-2004

SUPERSEDES: 01-23-2003

REVISION DATE: 08-21-2014

SUPERSEDES: 07-22-2004

TO THE BEST OF OUR KNOWLEDGE THE INFORMATION CONTAINED HEREIN IS ACCURATE AS OF THE DATE HEREOF. ANY DETERMINATION AS TO THE SUITABILITY OF THE PRODUCT FOR ANY PARTICULAR PURPOSE, ITS SAFE USE OR DISPOSAL, SHALL BE THE RESPONSIBILITY OF THE USER. THE INFORMATION CONTAINED HEREIN IS IN NO WAY INTENDED TO SUPPLEMENT, MODIFY, OR SUPERSEDE THE INFORMATION PROVIDED IN THE PRODUCT PACKAGE INSERT WITH RESPECT TO THE USE OF THE PRODUCT FOR MEDICAL PURPOSES. PLEASE REFER TO THE PRODUCT PACKAGE INSERT FOR INFORMATION REGARDING THE USE OF THE PRODUCT FOR MEDICAL PURPOSES.

#03
p.1**Material Safety Data Sheet**

May be used to comply with
OSHA's Hazard Communication Standard,
29 CFR 1910.1200. Standard must be
consulted for specific requirements.

U.S. Department of Labor

Occupational Safety and Health Administration
(Non-Mandatory Form)
Form Approved
OMB No.

Identity: **BACITRACIN OINTMENT**
Product Number: D060

SECTION I

Manufacturer's Name:
Clay Park Labs, Inc.

Address:
1700 Bathgate Avenue
Bronx, NY 10457-5000

Emergency Number
718-960-9978

General Information
Shabbir Barot:
718-960-9943

Date Prepared: 11/01/00

Signature of Preparer (optional):

SECTION II - INFORMATION ON INGREDIENTS

Ingredient: BACITRACIN
Ingredient Sequence Number: 01
CAS Number: 1405-87-4
NIOSH (RTECS) Number: CP0175000

Ingredient: LIGHT MINERAL OIL (BLANDOL)
Ingredient Sequence Number: 02
CAS Number: 8042-47-5
NIOSH (RTECS) Number: PY8030000

Ingredient: WHITE PETROLATUM (PETROLATUM, GREASE *93-3 *)
Ingredient Sequence Number: 03
CAS Number: 8009-03-8
NIOSH (RTECS) Number: 1000032PL

I- 498019 C-45802016070
I- 49802 C-45802016013
I- 490553 C-45802006001
D6M I- 245566 C-45802006070
p6m I- 245563 C-45802006003

SECTION III - PHYSICAL/CHEMICAL CHARACTERISTICS

Boiling Point: N/A

Specific Gravity (H₂O = 1): N/A

Vapor Pressure (mm Hg 20°C): N/A

Melting Point: N/A

Vapor Density (AIR = 1): N/A

Evaporation Rate: N/A
(Diethyl Ether = 1)

Solubility in Water: Insoluble

Appearance and Odor: Pale, yellow ointment with little or no odor.

#03
p.2**SECTION IV – FIRE AND EXPLOSION HAZARD DATA****Flash Point:** N/A**Extinguishing Media:** Water, dry chemical, foam.**Special Fire Fighting Procedures:** Wear SCBA and full protective equipment. Fight fire from a safe distance.**Unusual Fire and Explosion Hazards:** Irritating and highly toxic gases may be generated by thermal decomposition or combustion.**SECTION V – REACTIVITY DATA****Stability:** YES**Conditions/Materials to Avoid:** NONE**Hazardous Decomp. Products:** N/A**Hazardous Poly. Occur:** NO**SECTION VI – HEALTH HAZARD DATA****Route(s) of Entry:** Inhalation? NO Skin? YES Ingestion? NO
Health Hazards (Acute and Chronic): For external use only. Do not use in eyes. In case of deep puncture wounds, animal bites, serious wounds, or serious burns, consult a doctor. Do not use for more than one week.**Signs and Symptoms of Exposure:** N/A**Medical Conditions Generally Aggravated by Exposure:** N/A**Emergency/First Aid Procedures:** Obtain medical attention in all cases.**Carcinogenicity:** NTP? NO IARC? NO OSHA? NO**SECTION VII – PRECAUTIONS FOR SAFE HANDLING AND USE****Steps if Released/Spilled:** N/A**Neutralizing Agent:** N/A**Waste Disposal Method:** Dispose of IAW/Federal, State, and local regulations.**Precautions-Handling/Storage:** N/A**SECTION VIII – CONTROL MEASURES****Respiratory Protection:** N/A**Ventilation:** N/A**Protective Gloves:** N/A**Eye Protection:** N/A**Other Protective Clothing or Equipment:** N/A**Work/Hygiene Practices:** N/A**DISCLAIMER OF LIABILITY**

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Safety Data Sheet



Section 1: Identification

Product identifier

Product Name • **Bacitracin Zinc and Polymyxin B Sulfates Ophthalmic Ointment**
Product Code • AB07534; Core No. 075

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

Recommended use • Finished Pharmaceutical Product; For the treatment of superficial ocular infections involving the conjunctiva and/or cornea.
Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Bausch & Lomb
 1400 North Goodman Street
 Rochester, NY 14609
 United States
 bausch.com
Telephone (General) • 1-800-553-5340

Emergency telephone number

Manufacturer • 1-800-535-5053 - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Skin Sensitization 1B

Label elements

UN GHS

WARNING



Hazard statements • May cause an allergic skin reaction

Precautionary statements

Prevention • Wash thoroughly after handling.

Response • IF ON SKIN: Wash with plenty of soap and water.
If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse.

Storage/Disposal • Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Bacitracin Zinc	CAS:1405-89-6 EINECS:215-787-8	< 2%	UN GHS: NDA
Mineral oil	CAS:8012-95-1 EINECS:232-384-2	10% TO 15%	UN GHS: NDA
Polymyxin B sulfate	CAS:1405-20-5 EINECS:215-774-7	< 1%	UN GHS: NDA
White Petrolatum	CAS:8009-03-8 EINECS:232-373-2	> 80%	UN GHS: NDA

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention.

Skin

- Flush with fresh water if contact with skin or eyes. If skin irritation occurs: Get medical advice/attention.

Eye

- For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention. If eye irritation persists: Get medical advice/attention.

Ingestion

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • SMALL FIRES: Dry chemical, CO2, water spray or regular foam.
LARGE FIRE: Water spray, fog or regular foam.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known.

Hazardous Combustion Products • None known.

Advice for firefighters

- Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions • No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures • Keep unauthorized personnel away. Ventilate closed spaces before entering. Stop leak if you can do it without risk.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures • Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Dispose of in accordance with Section 13.

Section 7 - Handling and Storage

Precautions for safe handling

Handling • No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

Storage • Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

Incompatible Materials or Ignition Sources • None specified.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines • Refer to the occupational exposure limits / guidelines for the individual product

components.

Exposure Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Mineral oil (8012-95-1)	STELs	Not established	10 mg/m3 STEV (mist)	10 mg/m3 STEL	Not established
	TWAs	5 mg/m3 TWA (excluding metal working fluids, highly & severely refined, inhalable fraction)	5 mg/m3 TWAEV (mist)	5 mg/m3 TWA	5 mg/m3 TWA

Exposure Control Notations

ACGIH

•Mineral oil (8012-95-1): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (highly and severely refined); A2 - Suspected Human Carcinogen (poorly and mildly refined))

Exposure controls

Engineering Measures/Controls

- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory

- In the event of a bulk spill, and where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. In the event of a spill, appropriate eye protection should be worn.

Hands

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile gloves.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

General Industrial Hygiene Considerations

Environmental Exposure Controls

- Wash thoroughly after handling.

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid Ointment	Appearance/Description	Translucent, off white to yellowish ointment.
Color	off-white to yellowish.	Odor	Not relevant
Aerosol Type	Not relevant	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	No data available
Decomposition Temperature	No data available	pH	Not relevant
Specific Gravity/Relative Density	Not relevant	Water Solubility	Immiscible
Viscosity	No data available		

Volatility

Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		

Flammability

Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant

Environmental

Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity**Reactivity**

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information**Information on toxicological effects**

Components		
Polymyxin B sulfate (< 1%)	1405-20-5	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 790 mg/kg
White Petrolatum (> 80%)	8009-03-8	Acute Toxicity: Intraperitoneal-Mouse LD50 • >50 g/kg
Mineral oil (10% TO 15%)	8012-95-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • >24 g/kg; Gastrointestinal: Hypermotility, diarrhea

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Skin Sensitizer 1B
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met

Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met

Potential Health Effects

Inhalation

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • No data available.

Skin

- Acute (Immediate)** • Not expected to cause skin irritation.
- Chronic (Delayed)** • Repeated and prolonged exposure may cause sensitization.

Eye

- Acute (Immediate)** • Non-irritating to the eyes when used as directed.
- Chronic (Delayed)** • Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects. Under normal conditions of use, no health effects are expected.

Ingestion

- Acute (Immediate)** • Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.
- Chronic (Delayed)** • No data available.

Reproductive Effects

- Polymyxin B has been reported to impair the motility of equine sperm, but its effects on male or female fertility are unknown.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available.

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	not regulated	NDA	NDA	NDA
TDG	NDA	not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	not regulated	NDA	NDA	NDA

Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

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

SARA Hazard Classifications • No data available

Inventory						
Component	CAS	Canada DSL	Canada NDSL	EU EINECS	EU ELNICS	TSCA
Mineral oil	8012-95-1	Yes	No	Yes	No	Yes
White Petrolatum	8009-03-8	Yes	No	Yes	No	Yes
Polymyxin B sulfate	1405-20-5	Yes	No	Yes	No	No
Bacitracin Zinc	1405-89-6	No	Yes	Yes	No	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Polymyxin B sulfate	1405-20-5	Not Listed
• White Petrolatum	8009-03-8	Uncontrolled product according to WHMIS classification criteria
• Bacitracin Zinc	1405-89-6	Not Listed
• Mineral oil	8012-95-1	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Polymyxin B sulfate	1405-20-5	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Bacitracin Zinc	1405-89-6	Not Listed
• Mineral oil	8012-95-1	1 %

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• Polymyxin B sulfate	1405-20-5	Not Listed
• White Petrolatum	8009-03-8	Carc.Cat.2; R45
• Bacitracin Zinc	1405-89-6	Not Listed
• Mineral oil	8012-95-1	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Polymyxin B sulfate	1405-20-5	Not Listed
• White Petrolatum	8009-03-8	T R:45 S:53-45
• Bacitracin Zinc	1405-89-6	Not Listed
• Mineral oil	8012-95-1	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Notes - Substances and Preparations

• Polymyxin B sulfate	1405-20-5	Not Listed
• White Petrolatum	8009-03-8	N
• Bacitracin Zinc	1405-89-6	Not Listed
• Mineral oil	8012-95-1	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Polymyxin B sulfate	1405-20-5	Not Listed
• White Petrolatum	8009-03-8	S:53-45
• Bacitracin Zinc	1405-89-6	Not Listed
• Mineral oil	8012-95-1	Not Listed

United States**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Polymyxin B sulfate	1405-20-5	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Bacitracin Zinc	1405-89-6	Not Listed
• Mineral oil	8012-95-1	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Polymyxin B sulfate	1405-20-5	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Bacitracin Zinc	1405-89-6	Not Listed
• Mineral oil	8012-95-1	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Polymyxin B sulfate	1405-20-5	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Bacitracin Zinc	1405-89-6	Not Listed
• Mineral oil	8012-95-1	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Polymyxin B sulfate	1405-20-5	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Bacitracin Zinc	1405-89-6	Not Listed
• Mineral oil	8012-95-1	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Polymyxin B sulfate	1405-20-5	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Bacitracin Zinc	1405-89-6	Not Listed
• Mineral oil	8012-95-1	Not Listed

Section 16 - Other Information

Last Revision Date	• 14/May/2015
Preparation Date	• 14/May/2015
Disclaimer/Statement of Liability	• To the best of our knowledge, the information contained herein is accurate. However, neither Bausch & Lomb, Inc. 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. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Bausch & Lomb, Inc. or any of its subsidiaries be liable for any special, incidental or consequential damages.

Revised: 5/23/2016

SAFETY DATA SHEET

Page 1 of 6



Humco Holding Group, Inc.
7400 Alumax Dr
Texarkana TX 75501 USA
800-662-3435
cs@humco.com
www.humco.com

24-Hour Emergency Number (CHEMTREC)
USA- 800-424-9300
International – 703-527-3887

All non-emergency calls should be directed to
Customer Service at 800-662-3435

NAME: BENZOIN COMPOUND TINCTURE, USP

SDS NO. 0243

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Benzoin Compound Tincture, USP

Synonyms: Benzoin Tincture

Recommended Use: Oral mucosal protectant, wound dressing

Manufacturer by: Humco Holding Group, Inc.

7400 Alumax Dr
Texarkana TX 75501 USA
800-662-3435
cs@humco.com
www.humco.com

24-Hour Emergency Number (CHEMTREC)

USA- 800-424-9300

International – 703-527-3887

All non-emergency calls should be directed to Customer Service at 800-662-3435

2. HAZARD IDENTIFICATION

Pictogram:	
Classification:	Flammable liquid category 3
Signal Word:	Danger, Health Hazard
Hazard Statements:	Flammable liquid and vapor. May be skin and eye irritant, harmful if swallowed

3. COMPOSITION / INGREDIENTS

CHEMICAL NAME	CAS#
ALCOHOL	64-17-5
BENZOIN	91845-21-5
STORAX	8046-19-3

TOLU BALSAM	9000-64-0
ALOE	Not Available

The exact percentage has been withheld as a trade secret

4. FIRST-AID MEASURES

ROUTE	COMMON SYMPTOMS	FIRST AID
Inhalation	Over exposure to vapors may cause irritation to the nose, throat, and respiratory tract. Headache and drowsiness may occur.	Remove source of contamination or move victim to fresh air. If affected person is not breathing, apply artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.
Ingestion	Vomiting, Nausea, diarrhea, drowsiness, narcosis	Considered to be toxic (Ethyl Alcohol). Do NOT induce vomiting unless directed to so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing. Call Poison Control Center. Get medical attention or advice immediately.
Skin	May cause dermal irritation	If irritation occurs, wash with disinfectant soap and water. Wash clothing before reuse. If irritation persists, get medical attention.
Eyes	Irritation	Immediately flush eyes with water for at least 15 minutes while holding eyelids open. Consult a physician.

5. FIRE-FIGHTING MEASURES

Flash Point:	64.4 °F (Open Cup)
Auto Ignition:	The lowest know value is 685.4 °F (Ethyl alcohol 200 proof)
Extinguishing Media:	Use methods appropriate for the surrounding fire. Consider water spray or fog, carbon dioxide, dry chemical powder, or alcohol resistant foam.
Products of Combustion:	Upon combustion this product, it may emit carbon dioxide and carbon monoxide.
Fire Fighting Equipment and Procedures:	Wear protective clothing and equipment suitable for the surrounding fire, including helmet, facemask, and self-contained breathing apparatus. LARGE FIRE: Use alcohol foam, water spray or fog. Cool containing vessels with water get in order to prevent pressure build-up, auto-ignition or explosion.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Read entire label before using and follow all label directions.
Environmental Precautions:	Prevent discharge to open waters.
Method of Containment:	Absorb spilled liquids in suitable inert material such as clay, vermiculite or diatomaceous earth.
Method for Clean-Up:	Ventilate area of spill or leak. Mop up and containerize in approved chemical waste container. Wash spill area with water.

7. HANDLING AND STORAGE

Handling:	Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. Stay away from ignition source. Do not take internally. Do not consume food, drink or smoke while handling this product. Keep away from oxidizing agents.
Storage:	Keep container tightly closed and in a dry, cool, and well ventilated place. Opened containers must be resealed and kept upright to prevent leakage. Keep away from all ignition source (sparks or flame).

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Engineering Controls:	Handle as per good industrial hygiene and safety practice. Use explosion proof ventilations as required to control vapor concentration. Ensure that eyewash station and safety showers are in adequate location.
Personal Protective Equipment (PPE)	
Eye/Face Protection:	Use appropriate face shield and approved splash goggles.
Skin Protection:	Handle with approved gloves. Impervious clothing, flame retardant antistatic protective clothing is recommended to protect from body contact.
Respiratory Protection	Use either an atmosphere supplying respirator or an air purifying respirator for organic vapors. If permissible exposure level is exceeded, use NIOSH approved respirator.
General Hygiene Considerations:	Wash hands after use. Eye wash fountains and safety showers are generally required for emergency use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Dark brown liquid	Upper/Lower Flammability:	Not determined
Odor:	Characteristic odor	Vapor Pressure (mmHg)	Not determined
Odor Threshold:	Not determined	Vapor Density (air = 1)	Not determined
pH:	Not determined	Relative Density (H₂O=1):	0.88 @ 25°C
Melting point /Freezing Point:	Not determined	Solubility (in water):	insoluble
Boiling point/range:	Not determined	Partition coefficient: n-octanol/water:	Not determined
Flash point	64.4 °F	Auto-ignition temperature	The lowest know value is 685.4 °F (Ethyl alcohol 200 proof)
Evaporation rate	Not determined	Decomposition Temperature:	Not determined
Flammability:	Flammable	Viscosity	Not determined

10. STABILITY AND RACTIVITY

Reactivity:	Not reactive but may react with strong oxidizing agents.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous reactions:	Not determined.
Conditions to Avoid:	Heat, sparks, open flame.
Incompatible materials:	Oxidizing agents, slightly reactive to acids, alkalis.
Hazardous Decomposition Products:	Carbon oxides (CO, CO ₂)

11. TOXICOLOGICAL INFORMATION

Acute toxicity:	Humans: May be irritant in case of skin contact, of ingestion, of inhalation. May affect central nervous system (CNS).
Skin irritation:	Slightly irritates to the skin.
Eye contact damage:	Moderately irritating to the eyes.
Respiratory damage:	May cause irritation to respiratory tract.
Ingestion overdose:	May affect central nervous system (restlessness, excitement, drowsiness, weakness, headache, unconscious etc.), may affect metabolism, blood, gastro system, liver. May affect urinary and cardiovascular systems.
Delayed, immediate, or chronic effects from short- and long-term exposure	Prolonged exposure may cause drying, defatting, and irritation. Chronic exposure by ingestion may cause damage in liver.

LD50	3450 mg/kg mouse; 7060 mg/kg rat – Ethyl alcohol
Symptoms associated with exposure:	May cause skin and eye irritation.
Carcinogenicity:	
OSHA:	Not listed
NTP:	Not listed
IARC:	Not listed

12. ECOLOGICAL INFORMATION

Acute or chronic aquatic toxicity:	Not determined.
Chemical degradation:	Not determined.
Biodegradation:	Not determined.
Bioaccumulation potential	Not determined.
Adsorption studies or leaching studies:	Not determined.
Other adverse effects	Not determined.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with federal, state and local laws and regulations. Avoid release into environment.

14. TRANSPORT INFORMATION

DOT Hazard Classification:	Tinctures, Medicinal Flammable
UN number:	1293
UN proper shipping name:	Not available
Transport hazard class(es):	Not available
Packing group number:	II
Environmental hazards:	Not applicable
Special precautions:	Keep away from heat, sparks, and ignition sources.

15. REGULATORY INFORMATION

Not determined

16. OTHER INFORMATION

The information in this SDS is considered current and reliable. However, the data is provided without any warranty, expressed or implied, regarding its correctness or accuracy. Since the conditions for use, handling, storage and disposal are beyond Humco's control, it is the

responsibility of the user to determine safe conditions for use and to assume liability for loss, damage, or expenses arising from improper use. No warranty expressed or implied regarding the product described herein will be created by or inferred from any statement or omission. Various agencies may have specific regulations concerning the transportation, handling, storage, use or disposal of this product which may not be reflected in the SDS. The user should review these regulations to ensure full compliance.



AprilFresh Biological Odor Eliminator

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 09/13/2016

Version: 2.0

SECTION 1: Product and Company Identification

1.1. Product identifier

Product name : AprilFresh Biological Odor Eliminator

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

Use of the substance/mixture : Deodorizer

Use only as directed.

1.3. Details of the supplier of the safety data sheet

Athena Medical Products
11270 Grooms Rd.
Suite B
Cincinnati, OH 45242

1.4. Emergency telephone number

Emergency number : (513) 900-1020

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (GHS)

Flam. Liq. 4 H227

Full text of H-phrases: see section 16

2.2. Label elements

GHS labeling

Signal word (GHS) : Warning
Hazard statements (GHS) : H227 - Combustible liquid
Precautionary statements (GHS) : P210 - Keep away from open flames, sparks, heat, hot surfaces. - No smoking
P280 - Wear eye protection, protective gloves
P370+P378 - In case of fire: Use Foam, powder, carbon dioxide (CO2), water spray to extinguish
P403+P235 - Store in a well-ventilated place. Keep cool
P501 - Dispose of contents/container to an authorized waste collection point

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

Component	CAS (Chemical Abstracts Service) number	%	Classification (GHS)
Non-hazardous components*		> 95	Not classified
Ethanol	64-17-5	< 3.4	Flam. Liq. 2, H225

*Chemical name, CAS number and/or exact concentration have been withheld as a trade secret

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation : Assure fresh air breathing. Allow the victim to rest.
First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Combustible liquid.

Explosion hazard : May form flammable/explosive vapor-air mixture.

Reactivity : Stable at ambient temperature and under normal conditions of use.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Remove ignition sources. Use special care to avoid static electric charges. No naked lights. No smoking.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Handle empty containers with care because residual vapors are flammable. Keep away from flames or sparks. - No smoking.

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapor. No naked lights. No smoking.

Handling temperature : 5 - 35 °C

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Proper grounding procedures to avoid static electricity should be followed.

Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Sources of ignition. Keep container closed when not in use. Keep in fireproof place.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight. Heat sources.

Storage temperature : 3 - 35 °C

7.3. Specific end use(s)

No additional information available

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according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

AprilFresh Biological Odor Eliminator		
ACGIH	Not applicable	
OSHA	Not applicable	
Non-hazardous components		
ACGIH	Not applicable	
OSHA	Not applicable	
Ethanol (64-17-5)		
ACGIH	ACGIH STEL (ppm)	1000 ppm
ACGIH	Remark (ACGIH)	URT irr
OSHA	OSHA PEL (TWA) (mg/m³)	1900 mg/m³
OSHA	OSHA PEL (TWA) (ppm)	1000 ppm

8.2. Exposure controls

Appropriate engineering controls	: Ensure good ventilation of the work station.
Personal protective equipment	: Avoid all unnecessary exposure.
Hand protection	: Wear protective gloves.
Eye protection	: Chemical goggles or safety glasses.
Respiratory protection	: Wear appropriate mask.
Other information	: Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear to slightly hazy.
Color	: Colorless
Odor	: Pleasant odour
Odor threshold	: No data available
pH	: 5 - 9
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: ≤ 0 °C
Freezing point	: ≤ 0 °C
Boiling point	: ≈ 100 °C
Flash point	: ≥ 65 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: ≈ 24.1 mm Hg @ 25°C
Relative vapor density at 20 °C	: No data available
Relative density	: ≈ 1
Specific gravity / density	: ≈ 8.34 lbs/gallon
Solubility	: Miscible with water.
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Heat from fire may generate flammable vapor.
Oxidizing properties	: Not classified as oxidizing.
Explosive limits	: No data available

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9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable at ambient temperature and under normal conditions of use.

10.2. Chemical stability

Combustible liquid. May form flammable/explosive vapor-air mixture.

10.3. Possibility of hazardous reactions

None under normal use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures. Open flame. Overheating. Heat. Sparks.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Fumes. Carbon monoxide. Carbon dioxide. May release flammable gases.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Non-hazardous components	
LD50 oral rat	> 90 ml/kg
Ethanol (64-17-5)	
LD50 oral rat	10740 mg/kg body weight (Rat; OECD 401: Acute Oral Toxicity; Experimental value)
LD50 dermal rabbit	> 16000 mg/kg (Rabbit; Literature study)
ATE US (oral)	10740.000 mg/kg body weight

Skin corrosion/irritation : Not classified
pH: 5 - 9

Serious eye damage/irritation : Not classified
pH: 5 - 9

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

Ethanol (64-17-5)	
LC50 fish 1	14200 mg/l (96 h; Pimephales promelas)
EC50 Daphnia 1	9300 mg/l (48 h; Daphnia magna)
LC50 fish 2	13000 mg/l 96 h; Salmo gairdneri (Oncorhynchus mykiss)
EC50 Daphnia 2	10800 mg/l (24 h; Daphnia magna)
Threshold limit other aquatic organisms 1	65 mg/l (72 h; Protozoa)
Threshold limit algae 1	1450 mg/l (192 h; Microcystis aeruginosa; Growth rate)
Threshold limit algae 2	5000 mg/l (168 h; Scenedesmus quadricauda; Growth rate)

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12.2. Persistence and degradability

AprilFresh Biological Odor Eliminator	
Persistence and degradability	Inherently biodegradable.
Ethanol (64-17-5)	
Persistence and degradability	Readily biodegradable in water. Biodegradable in the soil. Highly mobile in soil.
Biochemical oxygen demand (BOD)	0.8 - 0.967 g O ₂ /g substance
Chemical oxygen demand (COD)	1.70 g O ₂ /g substance
ThOD	2.10 g O ₂ /g substance
BOD (% of ThOD)	0.43 % ThOD

12.3. Bioaccumulative potential

AprilFresh Biological Odor Eliminator	
Bioaccumulative potential	Not established.
Ethanol (64-17-5)	
BCF fish 1	1 (72 h; Cyprinus carpio)
Log Pow	-0.31 (Experimental value)
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).

12.4. Mobility in soil

Ethanol (64-17-5)	
Surface tension	0.022 N/m (20 °C)

12.5. Other adverse effects

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to an approved waste disposal plant.

Additional information : Handle empty containers with care because residual vapors are flammable.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with US Dept. of Transportation (DOT)

Not regulated for transport

Additional information

Other information : This product is NOT REGULATED for transport per 49 CFR § 173.150(f)(2) when in containers of less than 119 gallon capacity.

SECTION 15: Regulatory information

15.1. US Federal regulations

AprilFresh Biological Odor Eliminator	
SARA Section 311/312 Hazard Classes	Fire 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.

15.3. US State regulations

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Ethanol (64-17-5)

U.S. - New Jersey - Right to Know Hazardous Substance List

SECTION 16: Other information

Full text of H-phrases:

Flam. Liq. 2	Flammable liquids Category 2
Flam. Liq. 4	Flammable liquids Category 4
H225	Highly flammable liquid and vapor
H227	Combustible liquid

HMIS III Rating

Health : 1 Slight Hazard - Irritation or minor reversible injury possible
Flammability : 2 Moderate Hazard
Physical : 0 Minimal Hazard
Personal protection : B

Athena SDS US (GHS HazCom 2012)

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



CaviWipes™
Date Prepared: 3/23/16

SAFETY DATA SHEET

Section 1. Product And Company Identification

Product Name: CaviWipes™

Product Use: Hard surface cleaner and disinfectant wipe

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

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

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

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

Section 2. Hazards Identification

GHS / HAZCOM 2012 Classification:

Flammable Liquid Category 3

Eye Irritation Category 2A

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

Warning!



Hazard Phrases

Flammable liquid and vapor.

Causes serious eye irritation.

May cause drowsiness or dizziness.

Prevention:

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

Keep container tightly closed.

Use explosion-proof electrical, ventilating and light equipment.

Take precautionary measures against static discharge.

Avoid breathing vapors.

Wash thoroughly after handling.

Use only outdoors or in a well-ventilated area.

Wear eye protection.



CaviWipes™
Date Prepared: 3/23/16

Response:

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

Call a POISON CENTER or physician if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. If eye irritation persists get medical attention.

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

Storage

Store in a well ventilated place. Keep cool.

Disposal

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

Other hazards: None

Section 3. Composition/Information On Ingredients

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

Section 4. First Aid Measures

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

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

Eye Contact: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

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

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



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

Section 5. Fire Fighting Measures

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

Specific Hazards Arising from the Chemical: Liquid saturant is a flammable liquid and vapor. Flammable vapors may collect in confined areas if large amounts are used.

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

Section 6: Accidental Release Measures

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

Environmental Precautions: Avoid release to the environment.

Methods and Materials for Containment and Cleaning up: Eliminate all ignition sources. Ventilate area. Use explosion-proof equipment if large amounts are released. Stop leak if it is safe to do so and move containers from the spill area. Collect material with an inert absorbent material and place in appropriate, labeled container for disposal. Do not reuse towelette.

Section 7. Handling and Storage

Precautions for Safe Handling: Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Liquid saturant is a flammable liquid and vapor. Keep away from heat, sparks, open flames and all other sources of ignition. Keep containers closed when not in use. Do not reuse towelette.

Conditions for Safe Storage, Including any Incompatibilities: Store in a cool, well ventilated area away from heat, oxidizers and all sources of ignition.



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Date Prepared: 3/23/16

Section 8. Exposure Controls / Personal Protection

Exposure Limits

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

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

Respiratory Protection: None under normal use conditions with adequate ventilation. For operations where the occupational exposure limits are exceeded, a NIOSH approved respirator with an organic vapor cartridges or supplied air respirator is recommended. Equipment selection depends on contaminant type and concentration. Select in accordance with 29 CFR 1910.134 and good industrial hygiene practice. For firefighting, use self-contained breathing apparatus.

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

Eye Protection: None required for normal use. If liquid splashing is possible, wear splash proof goggles to prevent eye contact.

Skin Protection: None required for normal use. Wear protective clothing if needed to avoid prolonged/repeated skin contact. Contaminated clothing should be removed and laundered before re-use.

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



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Section 9. Physical and Chemical Properties

The following data applies to the liquid saturant.

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

Section 10. Stability and Reactivity

Reactivity: Not reactive at ambient temperatures.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: Not reactive.

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

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

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

Section 11. Toxicological Information

Potential Health Effects:

The following applies to the liquid saturant. The towelette is not hazardous.

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

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



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

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

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

Medical Conditions Aggravated By Exposure: None currently known.

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

Acute Toxicity Values for OPA/Quat Solution:

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

Section 12. Ecological Information

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

Toxicity: No toxicity data available for product.

Isopropanol: LC50 fathead minnows 11,130 mg/L/48 hr; LC50 brown shrimp 1400 mg/L/48 hr
Diisobutylphenoxyethoxyethyltrimethylbenzylammonium chloride: LC50 pimephales promelas 1.6 mg/L/96 hr, LC50 leptomis macrochirus 1.4 mg/L/96 hr.

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

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

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

Other Adverse Effects: None known

Section 13. Disposal Considerations

Towelette Disposal: Do not reuse towelette. Dispose of used towelette in trash. Do not flush wipes down toilet.

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



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Date Prepared: 3/23/16

Section 14. Transport Information

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

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

Special precautions: None identified

Section 15. Regulatory Information

U.S. Federal Regulations:

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

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

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

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

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

US EPA Registered Pesticide: This chemical is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use.

CAUTION!
Harmful if absorbed through the skin.
Causes moderate eye irritation.



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Keep out of reach of children.

International Inventories

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

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

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

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

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

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

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

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

Section 16. Other Information

Effective Date: March 23, 2016

Supersedes Date: June 8, 2015

Revision Summary: Prop 65 removed per exposure assessment

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



SAFETY DATA SHEET

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Version: 1.0

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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

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

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

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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.

SAFETY DATA SHEET

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

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

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: 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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Ceftriaxone sodium

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

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

Flammability:

Autoignition Temperature (Solid) (°C):

No data available

SAFETY DATA SHEET

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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 Intravenous 586 mg/kg/day NOAEL No effects at maximum dose

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

Ceftriaxone sodium

SAFETY DATA SHEET

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

SAFETY DATA SHEET

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

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	Ceftriaxone for Injection USP 250 mg, 500 mg, 1 g and 2 g
Manufacturer	Lupin Limited Mandideep 462 046 INDIA
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

Section 2, Hazard(s) identification

Fire and Explosion	Expected to be non-combustible.
Health	Ceftriaxone for injection is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/ Information on Ingredients

Section 3, Composition/information on ingredients

Ingredients	CAS
Ceftriaxone Sodium USP	73384-59-5

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water.

	Obtain medical attention.
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
Skin Contact	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
Eye Contact	Flush eyes with plenty of water. Get medical attention.
NOTES TO HEALTH PROFESSIONALS	
Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
OVERDOSAGE	In the case of overdosage, drug concentration would not be reduced by hemodialysis or peritoneal dialysis. There is no specific antidote. Treatment of overdosage should be symptomatic.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
Extinguishing Media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems.

Clean-up Methods	Collect and place it in a suitable, properly labeled container for recovery or disposal.
Section 7: Handling and Storage	
Section 7, Handling and storage	
Handling	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
Storage	Ceftriaxone for injection USP sterile powder should be stored at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature] and protected from light. After reconstitution, protection from normal light is not necessary. The color of solutions ranges from light yellow to amber, depending on the length of storage, concentration and diluent used.
Section 8: Exposure Controls/Personal Protection	
Section 8, Exposure controls/personal protection	
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.	
Section 9: Physical and Chemical Properties	
Section 9, Physical and chemical properties	
Physical Form	Ceftriaxone for injection USP is supplied as a sterile crystalline powder in glass vials. The following packages are available: Vials containing 250 mg equivalent of ceftriaxone. Box of 1 (NDC 68180-611-01) and box of 10 (NDC 68180-611-10). Vials containing 500 mg equivalent of ceftriaxone. Box of 1 (NDC 68180-622-01) and box of 10 (NDC 68180-622-10). Vials containing 1 g equivalent of ceftriaxone. Box of 1 (NDC 68180-633-01) and box of 10 (NDC 68180-633-10). Vials containing 2 g equivalent of ceftriaxone. Box of 10 (NDC 68180-644-10).
Section 10: Stability and Reactivity	
Section 10, Stability and reactivity	
Stable under recommended storage conditions.	

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Considering the maximum duration of treatment and the class of the compound, carcinogenicity studies with ceftriaxone in animals have not been performed. The maximum duration of animal toxicity studies was 6 months.

Mutagenesis

Genetic toxicology tests included the Ames test, a micronucleus test and a test for chromosomal aberrations in human lymphocytes cultured *in vitro* with ceftriaxone. Ceftriaxone showed no potential for mutagenic activity in these studies.

Impairment of Fertility

Ceftriaxone produced no impairment of fertility when given intravenously to rats at daily doses up to 586 mg/kg/day, approximately 20 times the recommended clinical dose of 2 g/day.

Section 12: Ecological Information

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

Section 16, Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this MSDS.



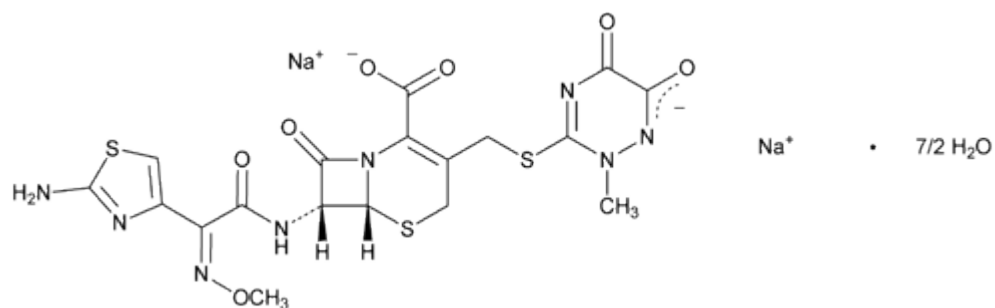
1. PRODUCT AND COMPANY INFORMATION

Distributed By: WG Critical Care, LLC.
120 Route 17 North
Suite 115
Paramus, NJ 07652 USA

Product Name: **Ceftriaxone for Injection, USP**

Active Ingredient/Primary Component: Ceftriaxone for Injection, USP

Structure:



Chemical Name: (1) 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[(2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-8-oxo-3-[[[(1,2,5,6-tetrahydro-2-methyl-5,6-dioxo-1,2,4-triazin-3-yl)thio]methyl]-, disodium salt, [6*R*]-[6*a*,7*b*(*Z*)]-, hydrate (2:7); (2) (6*R*,7*R*)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-8-oxo-3-[[[(1,2,5,6-tetrahydro-2-methyl-5,6-dioxo-*as*-triazin-3-yl)thio]methyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7²-(*Z*)-(O-methyloxime), disodium salt, sesquaterhydrate

Molecular Formula: C₁₈H₁₆N₈Na₂O₇S₃·3½H₂O

UNII Code: UNII-023Z5BR09K

CAS Number: 104376-79-6

Chemical Family: Antibacterial

Product Use: Pharmaceutical

Product Type: Prescription Drug

Container Information: Vials

Customer Service Phone Number: +1-888-493-0861

Emergency Phone Number: +1-866-562-4708 (Prosar)

WG Critical Care, LLC.

Ceftriaxone for Injection, USP	Safety Data Sheet (SDS)	
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2. HAZARDS IDENTIFICATION

PRIMARY PHYSICAL AND HEALTH HAZARDS: May cause irritations to the skin and eyes. May cause allergic reactions.

ROUTES OF ENTRY: Skin. Inhalation, Ingestion. Eye.

SIGNS & SYMPTOMS OF EXPOSURE: Acute signs and symptoms of exposure may include eye, skin, and respiratory irritation. May cause nausea, vomiting, abdominal pain, headache, dizziness, light headedness, or skin rash.

CHEMICAL LISTED AS CARCINOGEN: **NTP:** NO **IARC:** NO **OSHA:** NO

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>Weight %</u>	<u>CAS No.</u>
Ceftriaxone Sodium	100	104376-79-6

4. FIRST AID MEASURES

EYE EXPOSURE: Flush eyes with water for 10-20 minutes. Seek medical attention.

SKIN EXPOSURE: Remove contaminated clothing wash skin for 15-20 minutes with soap and water. Seek medical attention.

INGESTION: Do NOT induce vomiting. Flush mouth with water and seek medical attention immediately.

INHALATION: If there is breathing difficulty, remove from exposure and administer oxygen. See medical attention immediately.

NOTE TO PHYSICIAN: See patient package insert in shipping carton for complete information.

WG Critical Care, LLC.

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5. FIRE FIGHTING MEASURES

FLASH POINT:	Not Established
AUTO-IGNITION TEMPERATURE:	Not Established
FLAMMABLE LIMITS IN AIR:	Not Established
FLAMMABLE LIMITS:	Not Established
EXTINGUISHING MEDIA:	Water Spray, carbon dioxide, dry powder. Do not use a heavy stream of water.
UNUSUAL FIRE / EXPLOSION HAZARDS:	When heated to decomposition material, it emits toxic fumes: carbon monoxide, carbon dioxide, nitrogen oxides, sulfur compounds.

6. ACCIDENTAL RELEASE MEASURE

SPILL:	Contain and collect spillage and place in container for disposal according to local regulations (See Section 13). Wipe surface area clean with soap and water. Avoid contact with strong oxidizing agents.
RELEASE TO AIR:	Prevent release to environment. If aerosolized reduce exposure by ventilating area.
RELEASE TO WATER:	Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

7. HANDLING AND STORAGE

GENERAL HANDLING:	When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product. Keep away from sources of ignition.
STORAGE CONDITIONS:	Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F).

WG Critical Care, LLC.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATORY PROTECTION:	If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.
EYE PROTECTION:	Chemical goggles and/or face shield. Safety glasses are always required.
VENTILATION	Laboratory fume hood or local exhaust ventilation.
SKIN PROTECTION:	Work uniform or laboratory coat.
OTHER PROTECTIVE EQUIPMENT:	Protective Latex or Nitrile gloves
ADDITIONAL EXPOSURE PRECAUTIONS:	In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	Solid	SPECIFIC GRAVITY:	Not Established
APPEARANCE AND ODOR:	White to yellowish orange / N.D.	EVAPORATION RATE:	Not established
BOILING POINT:	Not established	MELTING POINT:	>155°C (decomposes)
VAPOR PRESSURE:	Not established	SOLUBILITY IN WATER:	Freely soluble
VAPOR DENSITY:	Not established	pH:	6.0-8.0

10. STABILITY AND REACTIVITY

STABILITY:	Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F).
INCOMPATIBILITY : (MATERIALS TO AVOID)	Strong oxidizing agents
HAZARDOUS POLYMERIZATION:	Will not occur
HAZARDOUS DECOMPOSITION:	When heated to decomposition material, it emits toxic fumes: carbon monoxide, carbon dioxide, nitrogen oxides, sulfur compounds.
CONDITIONS TO AVOID:	Avoid exposure to light, heat and strong oxidizing agents.

WG Critical Care, LLC.

Ceftriaxone for Injection, USP	Safety Data Sheet (SDS)	
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11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

COMPONENT	TYPE	ROUTE	SPECIES	DOSAGE
Ceftriaxone Sodium	LD ₅₀	Oral	Mouse	> 10g/kg
Ceftriaxone Sodium	LD ₅₀	Oral	Rat	>10g/kg
Ceftriaxone Sodium	LD ₅₀	Intravenous	Mouse	2.8g/kg
Ceftriaxone Sodium	LD ₅₀	Intravenous	Rat	2g/kg
Ceftriaxone Sodium	LD ₅₀	Intravenous	Rabbit	240mg/kg

12. ECOLOGICAL INFORMATION

No applicable information found.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

REGULATORY ORGANIZATIONS:

DOT: Not Regulated

ICAO / IATA: Not Regulated

15. REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

US Regulations

TSCA – No

CERCLA-No

SARA 302 – No

SARA 313 – No

OSHA Substance Specific - No

IMO: Not Regulated

WG Critical Care, LLC.

Ceftriaxone for Injection, USP	Safety Data Sheet (SDS)	
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16. OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

WG Critical Care, LLC.

Ceftriaxone for Injection, USP	Safety Data Sheet (SDS)	
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SAFETY DATA SHEET

Issuing Date 05-Jan-2015

Revision Date 16-Jun-2016

Revision Number 2

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

Product identifier

Product Name Clorox Healthcare® Citrace® Hospital Disinfectant & Deodorizer

Other means of identification

Synonyms None

EPA Pesticide registration number 67619-29

Recommended use of the chemical and restrictions on use

Recommended Use Disinfectant (Aerosol)

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Name The Clorox Professional Products Company

Supplier Address Clorox Professional Products Company
Broadway, CA 94612

Supplier Phone Number 1-510-271-7000

Emergency telephone number 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).

Serious eye damage/eye irritation	Category 2B
Carcinogenicity	Category 1B
Flammable Aerosols	Category 2
Gases Under Pressure	Compressed gas

GHS Label elements, including precautionary statements

Emergency Overview

Signal word Danger

Hazard Statements

Causes eye irritation
May cause cancer
Extremely flammable gas
Contains gas under pressure; may explode if heated

1289781 - Clorox Healthcare Citrace Hospital Disinfectant & Deodorizer

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Appearance Clear

Physical state Liquid

Odor Orange Citrus

Precautionary Statements - Prevention

Avoid breathing dust/fume/gas/mist/vapors/spray
 Contaminated work clothing should not be allowed out of the workplace
 Wear protective gloves
 Keep away from heat/sparks/open flames/hot surfaces. - No smoking
 Pressurized container: Do not pierce or burn, even after use
 Do not spray on an open flame or other ignition source

Precautionary Statements - Response

Specific treatment (see supplemental first aid instructions on this label)

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

Precautionary Statements - Storage

Store locked up
 Store in a well-ventilated place
 Do not expose to temperatures exceeding 122°F (50°C)

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

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

Other information

Causes mild skin irritation
 Harmful to aquatic life with long lasting effects
 Toxic to aquatic life
 Repeated or prolonged skin contact may cause allergic reactions with susceptible persons

Interactions with Other Chemicals

No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%	Trade Secret
Ethanol	64-17-5	50-70	*
Propane	74-98-6	1-5	*
D-Limonene	5989-27-5	1-5	*
Sodium nitrite	7632-00-0	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 thoroughly with plenty of water, also under the eyelids. If symptoms persist, call a physician.

Skin contact

Wash with soap and water. If symptoms persist, call a physician.

Inhalation

Remove to fresh air. If symptoms persist, call a physician.

Ingestion

Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Call a physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects

May cause redness and tearing of the 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

Containers may explode when heated.

Hazardous Combustion Products

No information available.

Explosion Data

Sensitivity to Mechanical Impact

No.

Sensitivity to Static Discharge

Yes.

Protective equipment and precautions for firefighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.
Other Information ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area).

Environmental precautions

Environmental precautions Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so. Keep out of drains, sewers, ditches and waterways.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid breathing vapors or mists. Contents under pressure. Do not puncture or incinerate cans. Avoid contact with eyes. Keep away from open flames, hot surfaces and sources of ignition.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children. Keep at a temperature not exceeding 50 °C. Keep away from open flames, hot surfaces and sources of ignition. Keep cool. Protect from sunlight.

Incompatible Products Strong oxidizing agents. Halogens. Acids.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Ethanol 64-17-5	STEL: 1000 ppm	TWA: 1000 ppm TWA: 1900 mg/m ³	IDLH: 3300 ppm 10% LELTWA: 1000 ppm TWA: 1900 mg/m ³
Propane 74-98-6	TWA: 1000 ppm	TWA: 1000 ppm TWA: 1800 mg/m ³	IDLH: 2100 ppm TWA: 1000 ppm TWA: 1800 mg/m ³
D-Limonene 5989-27-5	None	None	None
Sodium nitrite 7632-00-0	None	None	None

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

Other Exposure Guidelines

Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992) See section 15 for national exposure control parameters

Appropriate engineering controls

Engineering Measures Showers
 Eyewash stations
 Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin and body protection	Wear protective gloves and protective clothing.
Respiratory protection	If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke when using this product. Wash thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES**Physical and Chemical Properties**

Physical state	Liquid	Odor	Orange Citrus
Appearance	Clear	Odor Threshold	No information available
Color	Colorless		

Property	Values	Remarks	Method
pH	6.5-8.5	None known	
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	19°C (liquid, closed cup), Flame extension 18 inches (46 cm) without flashback	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air			
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	
Specific Gravity	0.85 (liquid)	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	No data available		
Oxidizing properties	No data available		

Other Information

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

10. STABILITY AND REACTIVITY

Reactivity

Can react with strong oxidizers, inorganic acids, and halogens.

Chemical stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

(Do not expose to temperatures exceeding 50°C/122°F). Protect from direct sunlight.

Incompatible materials

Strong oxidizing agents. Halogens. Acids.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	May be harmful by inhalation.
Eye contact	Irritating to eyes.
Skin contact	May cause irritation.
Ingestion	May cause central nervous system depression. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Ethanol 64-17-5	-	-	125 mg/L (Rat, 4 h)
Propane 74-98-6	-	-	658 mg/L (Rat) 4 h
D-Limonene 5989-27-5	4.4 g/kg (Rat)	>5 g/kg (Rabbit)	-
Sodium nitrite 7632-00-0	85 mg/kg (Rat)	-	5.5 mg/L (Rat)

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. Ethanol has been shown to be carcinogenic in long-term studies only when consumed as alcoholic beverage.

Chemical Name	ACGIH	IARC	NTP	OSHA
Ethanol 64-17-5	A3	Group 1	Known	X
D-Limonene 5989-27-5		Group 3		X
Sodium nitrite 7632-00-0		Group 2A		X

ACGIH (American Conference of Governmental Industrial Hygienists)

A3 - Animal Carcinogen

IARC (International Agency for Research on Cancer)

Group 1 - Carcinogenic to Humans

Group 2A - Probably Carcinogenic to Humans

Group 3 - Not Classifiable as to Carcinogenicity in Humans

NTP (National Toxicology Program)

Known - Known Carcinogen

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

Reproductive toxicity

No information available.

STOT - single exposure

No information available.

STOT - repeated exposure

No information available.

Chronic Toxicity

Contains a known or suspected carcinogen. Ethanol has been shown to be a reproductive toxin only when consumed as an alcoholic beverage.

Target Organ Effects

Eyes. Blood. Central nervous system (CNS). Liver. Respiratory system.

Aspiration Hazard

No information available.

Numerical measures of toxicity Product Information

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

ATEmix (oral)

63.6 g/kg

ATEmix (inhalation-gas)

10,425,493.31

ATEmix (inhalation-dust/mist)

188.00 mg/L

12. ECOLOGICAL INFORMATION

Ecotoxicity

Toxic to aquatic organisms. Harmful to aquatic life with long lasting effects.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Ethanol 64-17-5		LC50: 12.0 - 16.0 mL/L (96 h static) <i>Oncorhynchus mykiss</i> LC50: 13400 - 15100 mg/L (96 h flow-through) <i>Pimephales promelas</i> LC50: > 100 mg/L (96 h static) <i>Pimephales promelas</i>	EC50 = 34634 mg/L 30 min EC50 = 35470 mg/L 5 min	LC50: 9268 - 14221 mg/L (48 h) <i>Daphnia magna</i> EC50: 10800 mg/L (24 h) <i>Daphnia magna</i> EC50: 2 mg/L (48 h Static) <i>Daphnia magna</i>

Persistence and Degradability

No information available.

Bioaccumulation

Chemical Name	Log Pow
Ethanol 64-17-5	-0.32
Propane 74-98-6	2.3
Sodium nitrite 7632-00-0	-3.7

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal methods	Dispose of in accordance with federal, state and local regulations.
Contaminated Packaging	Dispose of in accordance with federal, state and local regulations.
US EPA Waste Number	D001

California Hazardous Waste Codes 232

This product contains one or more substances that are listed with the State of California as a hazardous waste.

14. TRANSPORT INFORMATION

DOT

Proper Shipping Name	CONSUMER COMMODITY
Hazard Class	ORM-D
Description	CONSUMER COMMODITY, ORM-D
Emergency Response Guide Number	126

TDG

Proper Shipping Name	AEROSOLS
Description	UN1950, AEROSOLS, 2.1

MEX

UN-No.	UN1950
Proper Shipping Name	AEROSOLS
Hazard Class	2.1
Description	UN1950, AEROSOLS, 2.1

ICAO

UN-No.	UN1950
Proper Shipping Name	AEROSOLS
Hazard Class	2.1
Description	UN1950, AEROSOLS, 2.1

IATA

UN-No.	UN1950
Proper Shipping Name	AEROSOLS, FLAMMABLE
Hazard Class	2.1
Packing Group	None
ERG Code	10L
Description	UN1950, AEROSOLS, FLAMMABLE, 2.1

IMDG/IMO

UN-No.	UN1950
Proper Shipping Name	AEROSOLS
Hazard Class	2
Packing Group	None
EmS-No.	F-D, S-U
Description	UN1950, AEROSOLS, 2.1

RID

UN-No.	UN1950
Proper Shipping Name	AEROSOLS
Hazard Class	2.1
Classification code	5F
Description	UN1950, AEROSOLS, 2.1

ADR

UN-No.	UN1950
Proper Shipping Name	AEROSOLS
Hazard Class	2.1
Classification code	5F
Tunnel restriction code	D
Description	UN1950, AEROSOLS, 2.1

ADN

UN-No.	UN1950
Proper Shipping Name	AEROSOLS
Hazard Class	2.1
Classification code	5F
Special Provisions	190, 327, 344, 625
Description	UN1950, AEROSOLS, 2.1
Hazard Labels	2.1
Limited Quantity	1 L
Ventilation	VE01, VE04

15. REGULATORY INFORMATION**International Inventories**

TSCA	Complies
DSL	All components are listed either on the DSL or NDSL.
IECSC	-

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 contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

Chemical Name	CAS No	Weight-%	SARA 313 - Threshold Values %
Sodium nitrite - 7632-00-0	7632-00-0	0.1-1	1.0

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	Yes
Sudden release of pressure hazard	Yes
Reactive Hazard	No

CWA (Clean Water Act)

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

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium nitrite 7632-00-0	100 lb.			X

CERCLA

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

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs	RQ
Sodium nitrite 7632-00-0	100 lb		RQ 100 lb final RQRQ 45.4 kg final RQ

US State Regulations**California Proposition 65**

This product contains the following Proposition 65 chemicals. Ethyl alcohol is only a considered a Proposition 65 developmental hazard when it is ingested as an alcoholic beverage.

Chemical Name	California Proposition 65
Ethanol - 64-17-5	Developmental

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Ethanol 64-17-5		X			
Propane 74-98-6	X	X	X		

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Revision Date 16-Jun-2016

D-Limonene 5989-27-5					X
Sodium nitrite 7632-00-0	X	X	X	X	

EPA Statement

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

EPA Pesticide label

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

International Regulations

Mexico

National occupational exposure limits

Mexico - Occupational Exposure Limits - Carcinogens

Canada

WHMIS Hazard Class

Not determined

16. OTHER INFORMATION

NFPA	Health Hazards	1	Flammability	3	Instability	0	Physical and Chemical Hazards	-
HMIS	Health Hazards	1	Flammability	3	Physical Hazard	0	Personal Protection	A

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

Issuing Date 05-Jan-2015

Revision Date 16-Jun-2016

Revision Note No information available

Disclaimer

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

End of Safety Data Sheet



SAFETY DATA SHEET

Issuing Date January 5, 2015

Revision Date New

Revision Number 0

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

Product identifier

Product Name Clorox® Broad Spectrum Quaternary Disinfectant Cleaner

Other means of identification

EPA Registration Number 67619-20

Recommended use of the chemical and restrictions on use

Recommended Use Multi-purpose spray cleaner and disinfectant

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Address

Clorox Professional Products 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 mixture 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 2B

GHS Label elements, including precautionary statements

Emergency Overview

Signal word	Warning
Hazard statements Causes mild skin irritation Causes eye irritation No pictogram required.	
Appearance Clear, colorless	Physical State Thin liquid
	Odor Slight solvent

Precautionary Statements - Prevention

Wash hands thoroughly after handling.

Precautionary Statements - Response

If skin irritation occurs: Get medical advice.

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

Precautionary Statements - Storage

None

Precautionary Statements - Disposal

None

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

Not applicable.

Other information

Harmful to aquatic life with long lasting effects.

Interactions with Other Chemicals

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %	Trade Secret
Diethylene glycol monobutyl ether	112-34-5	5 - 10	*
Tetrasodium ethylenediamine tetraacetate (EDTA)	64-02-8	1 - 5	*
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	85409-23-0	0.1 - 0.2	*
n-Alkyl (5% C12, 60% C14, 30% C16, 5% C18) dimethyl benzyl ammonium chloride	53516-76-0	0.1 - 0.2	*

* 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	Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Skin Contact	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
Inhalation	Move to fresh air. If breathing is affected, call a doctor.
Ingestion	Call a poison control center or doctor immediately for treatment advice. Have person sip a glassful of water if able to swallow. DO NOT induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Most Important Symptoms/Effects Mild irritation of eyes and skin.

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

Environmental precautions

Environmental Precautions	See Section 12 for additional ecological Information

Methods and material for containment and cleaning up

Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for Cleaning Up	Absorb and containerize. Wash residual down to sanitary sewer. Contact the sanitary treatment facility in advance to assure ability to process washed-down material.

7. HANDLING AND STORAGE

Precautions for safe handling

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

Conditions for safe storage, including any incompatibilities

Storage	Keep containers tightly closed in a dry, cool, and well-ventilated place.
Incompatible Products	None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Diethylene glycol monobutyl ether 112-34-5	None	None	None
Tetrasodium ethylenediamine tetraacetate (EDTA) 64-02-8	None	None	None
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride 85409-23-0	None	None	None
n-Alkyl (5% C12, 60% C14, 30% C16, 5% C18) dimethyl benzyl ammonium chloride 53516-76-0	None	None	None

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

Appropriate engineering controls

Engineering Measures	Showers Eyewash stations Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection	If splashes are likely to occur, wear safety glasses with side-shields. None required for consumer use.
Skin and Body Protection	Wear rubber or neoprene gloves for sensitive skin or if there is the potential for repeated or prolonged skin contact.
Respiratory Protection	If irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
Hygiene Measures	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	Slight solvent
Color	Colorless	Odor Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks/ Method</u>
pH	12 - 12.5	None known
Melting/freezing point	No data available	None known
Boiling Point/Range	No data available	None known
Flash Point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
Upper flammability limit	No data available	None known
Lower flammability limit	No data available	None known
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Specific Gravity	~1.0	None known
Water Solubility	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

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

None known.

Incompatible materials

None known.

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 irritation, nausea, vomiting, and diarrhea.

Component Information

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Diethylene glycol monobutyl ether 112-34-5	3384 mg/kg (Rat)	2700 mg/kg (Rabbit)	-

Information on toxicological effects

Symptoms May cause redness and tearing of the eyes and skin redness.

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	Contains no ingredient listed as a carcinogen.
Reproductive Toxicity	No information available
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Chronic Toxicity	No known effect.
Target Organ Effects	Respiratory system, eyes, skin, gastrointestinal tract (GI).

Aspiration Hazard No information available.

Numerical measures of toxicity Product Information

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

ATEmix (oral)

17.5 g/kg

ATEmix (dermal)

33.8 g/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

Harmful to aquatic life with long lasting effects.

Persistence and Degradability

No information available.

Bioaccumulation

No information available.

Other Adverse Effects

No information available.

13. DISPOSAL CONSIDERATIONS

Disposal methods

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

Contaminated Packaging

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

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

ICAO Not regulated

IATA Not regulated

IMDG/IMO Not regulated

15. REGULATORY INFORMATION

Chemical Inventories

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

DSL/NDSL All components are on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does the following chemical that is subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

Chemical Name	CAS-No	Weight %	SARA 313 - Threshold Values %
Diethylene glycol monobutyl ether (Glycol ethers category)	112-34-5	1 - 5	1.0

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 does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

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:

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

U.S. State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Diethylene glycol monobutyl ether (Glycol ethers category) 112-34-5	X		X		

International Regulations**Canada****WHMIS Hazard Class**

D2B Toxic Materials



16. OTHER INFORMATION

<u>NFPA</u>	Health Hazard 1	Flammability 0	Instability 0	Physical and Chemical Hazards -
<u>HMIS</u>	Health Hazard 1	Flammability 0	Physical Hazard 0	Personal Protection B

Prepared By	Product Stewardship 23 British American Blvd. Latham, NY 12110 1-800-572-6501
Preparation/Revision Date	January 5, 2015
Revision Date	New
Revision Note	New
Reference	CLX156311-001/156311.001

General Disclaimer

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

End of Safety Data Sheet



SDS DATE: 11.19.2015

SAFETY DATA SHEET

1. IDENTIFICATION

PRODUCT NAME: CONSULT FECAL OCCULT BLOOD TEST DEVELOPER
MFR #: 301

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

Other means of identification:

Component Name	Component Number
Consult Diagnostics Developer	551622

2. HAZARD IDENTIFICATION**Classification of the chemical:**

Component Name	GHS Classification	Hazard Statement
Consult Diagnostics Developer	Flammable (Category 2)	Flammable

Label elements:**Signal word:** Danger! Flammable**Precautionary statements:****Skin:** Cause skin irritation**Eye:** Cause eyedamage**Inhalation:** May be harmful if inhaled, may cause drowsiness or dizziness**Ingestion:** May be fatal or cause blindness if swallowed

Wear protective gloves/eye and face protection/protective clothing

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component Name	Chemical Name	CAS #	Concentration
Consult Diagnostics Developer	Denatured Ethanol Hydrogen Peroxide	NA 7722-84-1	70% <6%

NOTE: All other components present no significant physical or chemical hazard

4. FIRST AID MEASURES**Description of first aid measures:****Inhalation:** If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.**Skin contact:** Wash off with soap and plenty of water.**Eye contact:** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.**Ingestion:** Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIREFIGHTING MEASURES**Conditions of flammability:** Keep away from heat/spark/open flame/hot surface. No smoking.**Extinguishing media:** Use water spray, alcohol resistant foam, dry chemical or carbon dioxide.**Special hazards arising from the substance or mixture:** Carbon Oxides

Special protective equipment and precautions for firefighters: Wear self contained breathing apparatus for firefighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Use personal protective equipment. Ensure adequate ventilation. Remove all source of ignition. Evacuate personnel to safe areas. Do not let product enter drains.

Methods and materials for containment and cleaning up: Contain spillage, collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling: Use personal protective equipment. Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. Keep away from sources of ignition – No smoking.

Conditions for safe storage, including any incompatibilities: Keep containers tightly closed. Containers which are opened must be resealed.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits (AGGIH TLV & OSHA PEL):

Chemical Name	AGGIH TLV	OSHA PEL
Denatured Alcohol:		
Ethyl Alcohol	1000 ppm	1000 ppm
Methyl Alcohol	200 ppm	200 ppm
Hydrogen Peroxide	1 ppm	1 ppm

Exposure controls:

Respiratory protection: Use NIOSH approved respirators.

Skin protection: Wear appropriate protective gloves and suitable protective clothing.

Eye protection: Wear appropriate eye protection (safety glasses, goggles or face shield).

Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear colorless liquid

Odor: Mild, alcohol-like

Odor threshold: No data available

pH: No data available

Melting point/Freezing point: No data available

Initial boiling point and range: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas): No data available

Upper/lower flammability or explosive limits: No data available

Vapor pressure: No data available

Relative density: No data available

Solubility in water: Completely soluble

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

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity: No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical stability: Stable under recommended storage conditions.

Possibility of hazard reaction: Vapors may form explosive mixture in the air.

Conditions to avoid: Heat, flames and sparks. Extremes of temperature and direct sunlight.

Incompatible materials: Oxidizing agents.

Hazard decomposition products: In the event of fire: Carbon oxides

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure:****Toxicological data:**

LD 50: No data available

Carcinogenicity: No components of this product are listed as carcinogen by IARC, NTP or OSHA.

Potential health effects:

Skin: May be harmful if absorbed through skin. Cause skin irritation.

Eye: Cause eye irritation.

Inhalation: May be harmful if inhaled. Vapors may cause drowsiness and dizziness.

Ingestion: May be harmful if swallowed.

Other important toxicological hazards: To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

Eco-toxicity: No data available

Persistence and degradability: No data available

Bio-accumulative potential: No data available

Mobility in soil: No data available

Other adverse effects: No data available

13. DISPOSAL CONSIDERATION

Observe all federal, state and local regulations.

14. TRANSPORT INFORMATION



SDS DATE: 11.19.2015

DOT (US): NOTE: This product conforms to DOT Small Quantity Exception 49CFR173.4.

UN number:

UN proper shipping name:

Transport hazard class:

Packing group:

15. REGULATORY INFORMATION

US State Right to Know Laws:

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

Other US State "Right to Know" List: The following chemicals are listed by individual States:

Ethyl Alcohol (MA, PA, NJ)

Methyl Alcohol (MA, PA, NJ)

Hydrogen Peroxide (MA, PA, NJ)

16. OTHER INFORMATION

SDS Creation date: 7/23/2014

Revision #: 3

Disclaimer

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

Safety Data Sheet

Material Name: Curity Iodoform Packing Strips

SDS ID: COV-011

Section 1 - PRODUCT AND COMPANY IDENTIFICATION

Material Name

Curity Iodoform Packing Strips

Synonyms

7831, 7832, 7833, 7834

Product Use

Wound dressings

Restrictions on Use

For use under medical supervision only.

Manufacturer Information

Covidien, LP

15 Hampshire Street

Mansfield, MA 02048

USA

Phone: +1-(508) 261-8000 (Monday - Friday 8:00 am to 5:00 pm)

Email: customerservice@medtronic.com

Emergency Telephone Number:

CHEMTREC (800) 424-9300 (for US and Canada)

1(703) 527-3887 (Outside US and Canada)

Collect calls accepted

Section 2 - HAZARDS IDENTIFICATION

Classification in accordance with paragraph (d) of 29 CFR 1910.1200.

None needed according to classification criteria

GHS Label Elements

Symbol(s)

None needed according to classification criteria

Signal Word

None needed according to classification criteria

Hazard Statement(s)

None needed according to classification criteria

Precautionary Statement(s)

Prevention

None needed according to classification criteria

Response

None needed according to classification criteria

Safety Data Sheet

Material Name: Curity Iodoform Packing Strips

SDS ID: COV-011

Storage

None needed according to classification criteria

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations

Other Hazards

No additional information available.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

CAS	Component Name	Percent (%)
Trade Secret	Surfactant	1-10
Trade Secret	Polyol	1-10
75-47-8	Iodoform	1-10

Section 4 - FIRST AID MEASURES

Inhalation

It is unlikely that first aid will be required.

Skin

It is unlikely that first aid will be required.

Eyes

Rinse cautiously with water for several minutes. If eye irritation persists, get medical advice/attention.

Ingestion

Rinse mouth immediately and drink plenty of water. If swallowed, get medical attention.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.

Most Important Symptoms/Effects

Acute

May cause mild eye irritation. May cause skin irritation. Ingestion may cause irritation of the mouth and stomach.

Delayed

No information on significant adverse effects.

Safety Data Sheet

Material Name: Curity Iodoform Packing Strips

SDS ID: COV-011

Section 5 - FIRE FIGHTING MEASURES

Extinguishing Media**Suitable Extinguishing Media**

Use carbon dioxide, regular dry chemical, regular foam or water.

Unsuitable Extinguishing Media

None known.

Special Hazards Arising from the Chemical

Fumes from heating may cause irritation.

Hazardous Combustion Products

Oxides of carbon, oxides of iodine, hydroiodic acid

Fire Fighting Measures

Avoid inhalation of material or combustion by-products.

Section 6 - ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Wear personal protective clothing and equipment.

Methods and Materials for Containment and Cleaning Up

Clear up spills immediately and dispose of waste safely.

Environmental Precautions

Avoid release to the environment.

Section 7 - HANDLING AND STORAGE

Precautions for Safe Handling

Observe good hygiene and safety practices when handling this product.

Conditions for Safe Storage, Including any Incompatibilities

Store in a cool, dry place. Keep container tightly closed. Keep away from incompatible materials.

Incompatible Materials

Acids, bases, strong oxidizing agents

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Component Exposure Limits

Iodoform	75-47-8
ACGIH:	0.6 ppm TWA

Safety Data Sheet

Material Name: Curity Iodoform Packing Strips
SDS ID: COV-011

NIOSH:	0.6 ppm TWA; 10 mg/m ³ TWA
Mexico:	0.6 ppm TWA LMPE-PPT; 10 mg/m ³ TWA LMPE-PPT
	1 ppm STEL [LMPE-CT]; 20 mg/m ³ STEL [LMPE-CT]

Biological limit value

There are no biological limit values for any of this product's components.

Engineering Controls

Based on available information, additional ventilation is not required.

Individual Protection Measures, such as Personal Protective Equipment
Eye/face protection

Eye protection not required under normal conditions. Safety glasses or goggles are recommended when there is a potential for eye contact.

Skin Protection

Not required.

Respiratory Protection

No respirator is required under normal conditions of use.

Glove Recommendations

Not required.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Opaque light yellow fabric saturated with liquid	Physical State	Solid
Odor	Iodine	Color	Opaque, light yellow
Odor Threshold	Not available	pH	Not available
Melting Point	Not available	Boiling Point	Not available
Freezing point	Not available	Evaporation Rate	Not available
Boiling Point Range	Not available	Flammability (solid, gas)	Not available
Autoignition	Not available	Flash Point	Not available
Lower Explosive Limit	Not available	Decomposition	Not available
Upper Explosive Limit	Not available	Vapor Pressure	Not available
Vapor Density (air=1)	Not available	Specific Gravity (water=1)	Not available

Safety Data Sheet

Material Name: Curity Iodoform Packing Strips
SDS ID: COV-011

Water Solubility	Not available	Partition coefficient: n-octanol/water	Not available
Viscosity	Not available	Solubility (Other)	Not available
Density	Not available		

Other Information

No additional information available.

Section 10 - STABILITY AND REACTIVITY

Reactivity

Not known to occur.

Chemical Stability

Stable under normal conditions of use.

Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

Conditions to Avoid

Avoid contact with incompatible materials.

Incompatible Materials

Acids, bases, strong oxidizing agents

Hazardous decomposition products

Oxides of carbon, oxides of iodine, hydroiodic acid

Section 11 - TOXICOLOGICAL INFORMATION

Information on Likely Routes of Exposure
Inhalation

Not a likely route of exposure.

Skin Contact

Not a likely route of exposure. May cause skin irritation.

Eye Contact

Not a likely route of exposure. May cause mild eye irritation.

Ingestion

Ingestion may cause irritation of the mouth and stomach, vomiting.

Acute and Chronic Toxicity
Component Analysis - LD50/LC50

The components of this material have been reviewed in various sources and the following selected endpoints are published:

Surfactant (Trade Secret)

Oral LD50 Rat >10000 mg/kg (Safety Data Sheet)

Polyol (Trade Secret)

Safety Data Sheet

Material Name: Curity Iodoform Packing Strips

SDS ID: COV-011

Oral LD50 Rat 22 g/kg
 Dermal LD50 Rabbit >20 mL/kg
 Iodoform (75-47-8)
 Oral LD50 Rat 335 mg/kg
 Dermal LD50 Rabbit 1184 mg/kg
 Inhalation LC50 Rat 165 ppm 7 h

Immediate Effects

May cause mild eye irritation. May cause skin irritation.

Delayed Effects

Ingestion of large amounts may cause central nervous system depression, kidney and liver damage.

Irritation/Corrosivity Data

May cause mild eye irritation. May cause skin irritation.

Respiratory Sensitization

No data available.

Dermal Sensitization

No data available.

Component Carcinogenicity

None of this product's components are listed by ACGIH, IARC, NTP, DFG or OSHA

Germ Cell Mutagenicity

No data available.

Reproductive Toxicity

No data available.

Specific Target Organ Toxicity - Single Exposure

No target organs identified.

Specific Target Organ Toxicity - Repeated Exposure

No target organs identified.

Aspiration hazard

No data available.

Medical Conditions Aggravated by Exposure

Repeated and prolonged exposure to irritants may cause dermatitis.

Section 12 - ECOLOGICAL INFORMATION

Ecotoxicity

Harmful to aquatic life with long lasting effects. Avoid release to the environment.

Component Analysis - Aquatic Toxicity

Iodoform	75-47-8
Fish:	LC50 96 h Pimephales promelas 2.79 - 3.06 mg/L [flow-through]

Persistence and Degradability

No information available for the product.

Safety Data Sheet

Material Name: Curity Iodoform Packing Strips

SDS ID: COV-011

Bioaccumulative Potential

Low bioconcentration.

Mobility

Expected to have high mobility in soil.

Other Toxicity

No additional information available.

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Methods

Dispose in accordance with all applicable regulations.

Section 14 - TRANSPORT INFORMATION

US DOT Information:

Shipping Name: Not applicable

Hazard Class: Not applicable

UN/NA #: Not regulated

Packing Group: Not applicable

Required Label(s): Not applicable

Additional information: No additional information available

IATA Information:

Shipping Name: Not applicable

Hazard Class: Not applicable

UN#: Not regulated

Packing Group: Not applicable

Required Label(s): Not applicable

Additional information: Consult current IATA regulations prior to shipping by air

IMDG Information:

Shipping Name: Not applicable

Hazard Class: Not applicable

UN#: Not regulated

Packing Group: Not applicable

Required Label(s): Not applicable

Additional information: No additional information available

TDG Information:

Shipping Name: Not applicable

Hazard Class: Not applicable

UN#: Not regulated

Packing Group: Not applicable

Required Label(s): Not applicable

Additional information: No additional information available

Safety Data Sheet

Material Name: Curity Iodoform Packing Strips

SDS ID: COV-011

Section 15 - REGULATORY INFORMATION

U.S. Federal Regulations

None of this products components are listed under SARA Sections 302/304 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), CERCLA (40 CFR 302.4), TSCA 12(b).

Not listed under California Proposition 65

Canadian WHMIS Ingredient Disclosure List (IDL)

The components of this product are either not listed on the IDL or are present below the threshold limit listed on the IDL.

Section 16 - OTHER INFORMATION

Summary of Changes

New SDS: May 1, 2015

Key / Legend

ACGIH - American Conference of Governmental Industrial Hygienists; ADR - European Road Transport; AU - Australia; BOD - Biochemical Oxygen Demand; C - Celsius; CA - Canada; CAS - Chemical Abstracts Service; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CLP - Classification, Labelling, and Packaging; CN - China; CPR - Controlled Products Regulations; DFG - Deutsche Forschungsgemeinschaft; DOT - Department of Transportation; DSD - Dangerous Substance Directive; DSL - Domestic Substances List; EEC - European Economic Community; EINECS - European Inventory of Existing Commercial Chemical Substances; EPA - Environmental Protection Agency; EU - European Union; F - Fahrenheit; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; ICAO - International Civil Aviation Organization; IDL - Ingredient Disclosure List; IDLH - Immediately Dangerous to Life and Health; IMDG - International Maritime Dangerous Goods; JP - Japan; Kow - Octanol/water partition coefficient; KR - Korea; LEL - Lower Explosive Limit; LLV - Level Limit Value; LOLI - List Of Lists™ - ChemADVISOR's Regulatory Database; MAK - Maximum Concentration Value in the Workplace; MEL - Maximum Exposure Limits; NFPA - National Fire Protection Agency; NIOSH - National Institute for Occupational Safety and Health; NJTSR - New Jersey Trade Secret Registry; NTP - National Toxicology Program; NZ - New Zealand; OSHA - Occupational Safety and Health Administration; PH - Philippines; RCRA - Resource Conservation and Recovery Act; REACH - Registration, Evaluation, Authorisation, and restriction of Chemicals; RID - European Rail Transport; SARA - Superfund Amendments and Reauthorization Act; STEL - Short-term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; UEL - Upper Explosive Limit; US - United States; WHMIS - Workplace Hazardous Materials Information System

Other Information

Disclaimer:

The information and recommendations in this safety data sheet are based on sources believed to be accurate as of the date of issue. 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. Covidien LP makes NO WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED and usage of this safety data sheet shall not establish a legal, contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose. Covidien LP assumes no responsibility for injury to vendee or third party person proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Furthermore, Covidien LP assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed. Users should ensure that any use or disposal of the material is in accordance with applicable national, country, federal, state, and local laws, directives, orders and regulations.

Conforms to HazCom 2012/United States

SAFETY DATA SHEET

Cyanocobalamin Injection, USP

Section 1. Identification

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

Section 2. Hazards identification

OSHA/HCS status	: While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.
Classification of the substance or mixture	: Not classified.
GHS label elements	
Signal word	: No signal word.
Hazard statements	: No known significant effects or critical hazards.



KMK Regulatory Services

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

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Cyanocobalamin Injection, USP

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	82000 mg/kg
Inhalation (vapors)	733.3 mg/L

Section 12. Ecological information

Toxicity

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

Persistence and degradability

There is no data available.

Bioaccumulative potential

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

Mobility in soil

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





Cyanocobalamin Injection, USP

Section 12. Ecological information

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

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

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

AERG : Not applicable.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined
United States inventory (TSCA 8b): All components are listed or exempted.
Clean Water Act (CWA) 311: Sodium hydroxide; Hydrochloric acid

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



KMK Regulatory Services

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



Cyanocobalamin Injection, USP

Section 15. Regulatory information

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

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

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

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

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

SARA 313

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

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

State regulations

Massachusetts : The following components are listed: Benzyl alcohol

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : The following components are listed: Benzyl alcohol

California Prop. 65

No products were found.





Section 16. Other information

History

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

Version : 1

Prepared by : KMK Regulatory Services Inc.

Key to abbreviations

: ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

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

UN = United Nations

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.





BIO-PHARM Incorporated

Diphenhydramine HCl Oral Solution

Safety Data Sheet

Prepared according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision date: 07/09/2015

Supersedes: N/A

Version: 1.0

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

1.1. Product identifier

Product name : Diphenhydramine HCl Oral Solution
 Product form : Mixture
 Other means of identification : Pharmaceutical
 Active Ingredients: Each 5 ml contains:
 12.5 mg Diphenhydramine HCl

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

Use of the substance/mixture : Antihistamine

1.3. Details of the supplier of the safety data sheet

BIO-PHARM INC.
 2091 HARTEL STREET
 LEVITTOWN, PA 19057
 PHONE: (215) 949-3711

1.4. Emergency telephone number

Emergency number : 1-866-845-1611

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Skin Sens. 1 H317
 Repr. 2 H361

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US) :



GHS07

GHS08

Signal word (GHS-US) :

Warning

Hazard statements (GHS-US) :

H317 - May cause an allergic skin reaction
 H361 - Suspected of damaging fertility or the unborn child

Precautionary statements (GHS-US) :

P201 - Obtain special instructions before use
 P202 - Do not handle until all safety precautions have been read and understood
 P261 - Avoid breathing mist, fume
 P272 - Contaminated work clothing must not be allowed out of the workplace
 P280 - Wear eye protection, face protection, protective clothing, protective gloves
 P302+P352 - If on skin: Wash with plenty of soap and water
 P308+P313 - If exposed or concerned: Get medical advice/attention
 P321 - Specific treatment (see first aid instructions on this label)
 P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
 P362+P364 - Take off contaminated clothing and wash it before reuse
 P405 - Store locked up
 P501 - Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

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3.2. Mixture

Name	Product identifier	%
Diphenhydramine hydrochloride	(CAS No) 147-24-0	0.1 - 1
2,3-Pentanedione	(CAS No) 600-14-6	0.1 - 1
Benzaldehyde	(CAS No) 100-52-7	<= 0.1

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : If exposed or concerned, get medical attention/advice. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an unconscious person.
- First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if breathing is affected. If breathing is difficult, supply oxygen.
- First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes. If irritation develops or persists, get medical attention.
- First-aid measures after eye contact : IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do so. If pain, blinking, or irritation develops or persists, get medical attention. Continue rinsing.
- First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison control center or medical professional. Get medical attention if you feel unwell.

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

- Symptoms/injuries : May cause an allergic skin reaction. Suspected of damaging fertility or the unborn child.
- Symptoms/injuries after inhalation : May cause respiratory irritation.
- Symptoms/injuries after skin contact : May cause an allergic skin reaction.
- Symptoms/injuries after eye contact : Direct contact with the eyes is likely to be irritating.
- Symptoms/injuries after ingestion : May cause gastrointestinal irritation.
- Chronic symptoms : May cause an allergic skin reaction. Suspected of damaging fertility. Suspected of damaging the unborn child.

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

No additional information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Carbon dioxide. Dry chemical. Water spray.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Heating may cause a fire.
- Explosion hazard : Product is not explosive.
- Reactivity : No dangerous reactions known under normal conditions of use.

5.3. Advice for firefighters

- Precautionary measures fire : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not dispose of fire-fighting water in the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Evacuate area. Ventilate area. Keep upwind. Spill should be handled by trained clean-up crews properly equipped with respiratory equipment and full chemical protective gear (see Section 8).

6.1.1. For non-emergency personnel

- Protective equipment : Wear Protective equipment as described in Section 8.

6.1.2. For emergency responders

- Protective equipment : Wear suitable protective clothing, gloves and eye or face protection. Approved supplied-air respirator, in case of emergency.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- For containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

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Methods for cleaning up

: Take up liquid spill into absorbent material. Place in a suitable container for disposal in accordance with the waste regulations (see Section 13).

6.4. Reference to other sections

See Sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling

: Handle in accordance with good industrial hygiene and safety procedures. Do not handle until all safety precautions have been read and understood. Avoid contact with skin and eyes. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions

: Store in a dry, cool and well-ventilated place. Keep the container tightly closed.

Storage temperature

: 20 - 25 °C (68 - 77 °F)

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Diphenhydramine hydrochloride (147-24-0)	
Remark (ACGIH)	OELs not established
Remark (OSHA)	OELs not established
Benzaldehyde (100-52-7)	
Remark (ACGIH)	OELs not established
Remark (OSHA)	OELs not established
2,3-Pentanedione (600-14-6)	
Remark (ACGIH)	OELs not established
Remark (OSHA)	OELs not established

8.2. Exposure controls

Appropriate engineering controls

: Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Use explosion-proof equipment with flammable materials. Ensure adequate ventilation, especially in confined areas.

Personal protective equipment

: Gloves. Protective goggles. Protective clothing.



Hand protection

: Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Gloves should be classified under Standard EN 374 or ASTM F1296. Suggested glove materials are: Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate, PVC or vinyl. Suitable gloves for this specific application can be recommended by the glove supplier.

Eye protection

: Wear eye protection, including chemical splash goggles and a face shield when possibility exists for eye contact due to spraying liquid or airborne particles.

Skin and body protection

: Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure.

Respiratory protection

: Use NIOSH-approved dust/particulate respirator. Where vapor, mist, or dust exceed PELs or other applicable OELs, use NIOSH-approved respiratory protective equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state

: Liquid

Color

: Pink.

Odor

: No data available

Odor Threshold

: No data available

pH

: 4.4 - 5.4

Relative evaporation rate (butylacetate=1)

: No data available

Melting point

: No data available

Freezing point

: No data available

Boiling point

: No data available

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Flash point	: > 149 °C (300 °F) (COC)
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: 1.1 - 1.2
Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

Excessive heat.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Hydrocarbons.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Diphenhydramine hydrochloride (147-24-0)	
LD50 oral rat	500 mg/kg
Benzaldehyde (100-52-7)	
LD50 oral rat	800 mg/kg
LD50 dermal rabbit	> 1250 mg/kg
2,3-Pentanedione (600-14-6)	
LD50 oral rat	3000 mg/kg

Skin corrosion/irritation	: Not classified pH: 4.4 - 5.4
Serious eye damage/irritation	: Not classified pH: 4.4 - 5.4
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: May cause respiratory irritation.

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Symptoms/injuries after skin contact	: May cause an allergic skin reaction.
Symptoms/injuries after eye contact	: Direct contact with the eyes is likely to be irritating.
Symptoms/injuries after ingestion	: May cause gastrointestinal irritation.
Chronic symptoms	: May cause an allergic skin reaction. Suspected of damaging fertility. Suspected of damaging the unborn child.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No information available.

12.2. Persistence and degradability

Diphenhydramine HCl Oral Solution	
Persistence and degradability	No information available.

12.3. Bioaccumulative potential

Diphenhydramine HCl Oral Solution	
Bioaccumulative potential	No information available.

12.4. Mobility in soil

Diphenhydramine HCl Oral Solution	
Ecology - soil	No information available.

12.5. Other adverse effects

Other adverse effects : No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Obtain the consent of pollution control authorities before discharging to wastewater treatment plants.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

SECTION 14: Transport information

In accordance with DOT

Not hazardous for transport

Additional information

Other information : No supplementary information available.

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

Diphenhydramine HCl Oral Solution	
All chemical substances in this product are listed in the EPA (Environment Protection Agency) TSCA (Toxic Substances Control Act) Inventory or are exempt	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard Delayed (chronic) health hazard

15.2. International regulations

No additional information available.

15.3. US State regulations

California Proposition 65

This product does not contain any substances known to the state of California to cause cancer and/or reproductive harm.

Benzaldehyde (100-52-7)

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

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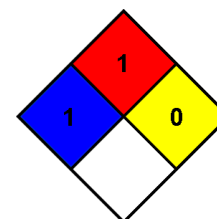
Glycerol (56-81-5)

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

SECTION 16: Other information

Indication of changes : Revision 1.0: New SDS Created.
Revision date : 07/09/2015
Other information : Author: BCS.

NFPA health hazard : 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.
NFPA fire hazard : 1 - Must be preheated before ignition can occur.
NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.



HMIS III Rating

Health : 1*
Flammability : 1
Physical : 0
Personal Protection : C

The information contained in this Safety Data Sheet has been compiled from reliable sources and is believed to be correct as of the date issued. It is the responsibility of the user to determine the appropriateness and applicability to their situation. BIO-PHARM INC. disclaims any expressed or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental, or consequential damages, from use or reliance on the above information.

Conforms to HazCom 2012/United States

SAFETY DATA SHEET

hikma.

Diphenhydramine Hydrochloride Injection, USP

Section 1. Identification

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

Pharmaceuticals.

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

Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.**Classification of the substance or mixture** : Not classified.**GHS label elements****Signal word** : No signal word.**Hazard statements** : No known significant effects or critical hazards.**Precautionary statements****Prevention** : Not applicable.**Response** : Not applicable.**Storage** : Not applicable.**Disposal** : Not applicable.**Hazards not otherwise classified** : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture**Other means of identification** : None.**CAS number/other identifiers**

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

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

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

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

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

Section 4. First aid measures**Description of necessary first aid measures**

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed**Potential acute health effects**

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

Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

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

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting 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 informationInformation on toxicological effectsAcute 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 exposureShort term exposure

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

Long term exposure



Section 11. Toxicological information

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

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

Potential chronic health effects

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	10000 mg/kg

Section 12. Ecological information

Toxicity

There is no data available.

Persistence and degradability

There is no data available.

Bioaccumulative potential

There is no data available.

Mobility in soil

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

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

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.



Diphenhydramine Hydrochloride Injection, USP

Section 14. Transport information

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

AERG : Not applicable.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

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

Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined
United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312



Diphenhydramine Hydrochloride Injection, USP

Section 15. Regulatory information

Classification : Not applicable.

Composition/information on ingredients

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

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

No products were found.

International regulations

International lists :

- Australia inventory (AICS)**: All components are listed or exempted.
- China inventory (IECSC)**: Not determined.
- Japan inventory**: All components are listed or exempted.
- Korea inventory**: Not determined.
- Malaysia Inventory (EHS Register)**: Not determined.
- New Zealand Inventory of Chemicals (NZIoC)**: All components are listed or exempted.
- Philippines inventory (PICCS)**: Not determined.
- Taiwan inventory (CSNN)**: Not determined.

Chemical Weapons Convention List Schedule I Chemicals : Not listed

Chemical Weapons Convention List Schedule II Chemicals : Not listed

Chemical Weapons Convention List Schedule III Chemicals : Not listed

Section 16. Other information

History

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

Version : 2

Prepared by : KMK Regulatory Services Inc.

Key to abbreviations :

- ATE = Acute Toxicity Estimate
- BCF = Bioconcentration Factor
- GHS = Globally Harmonized System of Classification and Labelling of Chemicals
- IATA = International Air Transport Association
- IBC = Intermediate Bulk Container
- IMDG = International Maritime Dangerous Goods
- LogPow = logarithm of the octanol/water partition coefficient
- MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)



Diphenhydramine Hydrochloride Injection, USP

Section 16. Other information

UN = United Nations

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Donnatal® Elixir Grape Flavored

SAFETY DATA SHEET

According to Federal Register/ Vol. 77, No.58/ Mon Mar 26, 2012/Rules & Regulations

Date of Issue: May 19, 2015, Supersedes: May 6, 2011 Version 1.0

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

1.1. Product identifier

Product form : Mixture
Trade name : Donnatal® Elixir Grape Flavored
Product code : 21-0100, 21-0200

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

Use only as per Product Monograph as a children's oral pharmaceutical product (see Product Monograph for further information).

1.3. Details of the supplier of the safety data sheet

IriSys, Inc.
8810 Rehco Road, Suite F
San Diego, CA 92121
USA

1.4. Emergency telephone number

Emergency number : 1-800-858-4006

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (GHS-US)

Eye Irrit. 2A	H319
Skin Sens. 1	H317
Carc. 2	H351
Repr. 1A	H360
STOT SE 3	H336
STOT SE 3	H335
ASP. TOX 1	H304

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :



Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H335 - May cause respiratory irritation
H336 - May cause drowsiness or dizziness
H351 - Suspected of causing cancer
H360 - May damage fertility or the unborn child
H304 - May be fatal if swallowed and enters airways

Precautionary statements (GHS-US) :

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P261 - Avoid breathing mist, vapors, spray
P264 - Wash clothing, hands, forearms and face thoroughly after handling
P271 - Use only outdoors or in a well-ventilated area
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear eye protection, face protection, protective clothing, protective gloves
P301 + P310 - If swallowed: Immediately call a poison center or doctor
P302 + P352 - If on skin: Wash with plenty of water
P304 + P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing
P305 + P351 + P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308 + P313 - If exposed or concerned: Get medical advice/attention
P312 - Call a doctor if you feel unwell
P331 - Do NOT induce vomiting
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

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P337 + P313 - If eye irritation persists: Get medical advice/attention
 P362 + P364 - Take off contaminated clothing and wash it before reuse
 P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
 P405 - Store locked up
 P501 - Dispose of contents/container to appropriate waste disposal sites in accordance with local, regional, national or international requirements.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Ethanol, ethyl alcohol	(CAS No) 64-17-5	Proprietary	Eye Irrit. 2A, H319 STOT SE 3, H336 STOT SE 3, H335 Asp. Tox. 1, H304
Phenobarbital	(CAS No) 50-06-6	0.28	Acute Tox. 3 (Oral), H301 Skin Sens. 1, H317 Carc. 2, H351 Repr. 1A, H360

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. Suspected of causing cancer. If exposed or concerned: Get medical advice/attention.
- First-aid measures after inhalation : Remove to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER/doctor/physician if you feel unwell.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
- First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

- Symptoms/injuries : May damage fertility or the unborn child.
- Symptoms/injuries after inhalation : May cause an allergic skin reaction. May cause respiratory irritation. May cause drowsiness or dizziness.
- Symptoms/injuries after eye contact : Causes serious eye irritation.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Will not normally support combustion.
- Explosion hazard : Not expected to present a significant hazard under anticipated conditions of normal use.
- Reactivity : Not expected to present a significant hazard under anticipated conditions of normal use.

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5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Avoid (reject) fire-fighting water to enter environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection. Avoid breathing vapors, mist, spray.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Contain and/or absorb spill with inert material (sand), then place in suitable container.
- Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapor. Avoid breathing vapors, mist, spray. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use only in a well-ventilated area.
- Hygiene measures : Wash hands, forearms and face thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep only in the original container in a cool, well ventilated place away from: Direct sunlight, incompatible materials. Keep container tightly closed. Store at 20°-25°C (68°-77°F) (see USP Controlled Temperature). Avoid freezing.
- Incompatible materials : Strong bases, strong acids, strong oxidizers, alkali metals, sodium hydroxide.
- Conditions to avoid : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

ethanol, ethyl alcohol (64-17-5)		
USA ACGIH	ACGIH STEL (ppm)	1000 ppm
USA ACGIH	Remark (ACGIH)	URT irr (Upper Respiratory Tract irritation)
USA OSHA	OSHA PEL (TWA) (mg/m³)	1900 mg/m³
USA OSHA	OSHA PEL (TWA) (ppm)	1000 ppm

8.2. Exposure controls

- Appropriate engineering controls : Ensure adequate ventilation.
- Personal protective equipment : Avoid all unnecessary exposure.
- Hand protection : Wear protective gloves (latex or nitrile)
- Eye protection : Chemical goggles or safety glasses.

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Respiratory protection : Where exposure through inhalation may occur from use, respiratory protection equipment is recommended.

Other information : When using, do not eat, drink or smoke.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Color : Clear; purple

Odor : Grape

Odor threshold : No data available

pH : 4,5 - 5,5

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

Melting point : No data available

Freezing point : No data available

Boiling point : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Flammability (solid, gas) : No data available

Vapor pressure : No data available

Relative vapor density at 20 °C : No data available

Relative density : 1.05-1.29 (specific gravity) @ 25°C

Solubility : Water: infinitely soluble

Log Pow : No data available

Log Kow : No data available

Viscosity, kinematic : No data available

Viscosity, dynamic : 15 cP @ 25°C

Explosive properties : No data available

Oxidizing properties : No data available

Explosive limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Not expected to present a significant hazard under anticipated conditions of normal use.

10.2. Chemical stability

Anticipated to be stable under anticipated conditions of normal use.

10.3. Possibility of hazardous reactions

Not expected to present a significant hazard under anticipated conditions of normal use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizers, alkali metals, sodium hydroxide.

10.6. Hazardous decomposition products

Fume, carbon monoxide, carbon dioxide, nitrogen oxides and may form small quantities of acrolein.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

ethanol, ethyl alcohol (64-17-5)

LD50 oral mouse	3450 mg/kg

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ethanol, ethyl alcohol (64-17-5)	
LD50 dermal rabbit	> 15800 mg/kg
LC50 inhalation mouse (ppm)	21000 ppm/4h

Phenobarbital	
LD50 oral mouse	112 mg/kg
LC50 inhalation rat (mg/l)	> 4100 µg/m³

Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Suspected of causing cancer.

Phenobarbital	
IARC group	2B - Possibly Carcinogenic to Humans Phenobarbital is carcinogenic in mice and rats after lifetime administration. In mice it produced benign and malignant liver cell tumors. In rats, benign liver cell tumors were observed. Phenobarbital was negative in a 26 week bioassay in p53 heterozygous mice. Genotoxicity studies for gene mutations and chromosome aberrations have given mixed results, however tests for DNA damage or repair have been negative.

Reproductive toxicity	: May damage fertility or the unborn child.
Specific target organ toxicity (single exposure)	: May cause drowsiness or dizziness. May cause respiratory irritation.
Specific target organ toxicity (repeated exposure)	: Not classified (Lack of data)
Aspiration hazard	: May be fatal if swallowed and enters airways.
Potential Adverse human health effects and symptoms	: See above. No additional health hazards are known.
Symptoms/injuries after inhalation	: May cause an allergic skin reaction. May cause respiratory irritation. May cause drowsiness or dizziness.
Symptoms/injuries after eye contact	: Causes serious eye irritation.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Not determined.

12.2. Persistence and degradability

DONNATAL ELIXIR - GRAPE	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

DONNATAL ELIXIR - GRAPE	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

DONNATAL ELIXIR - GRAPE	
Ecology - soil	Not determined.

12.5. Other adverse effects

Effect on ozone layer	: No additional information available
Effect on global warming	: Not determined.
Other information	: Avoid release to the environment.

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with DOT

Not determined

Additional information

Other information : No supplementary information available.

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

No additional information available

15.2. International regulations

CANADA

Not determined

EU-Regulations

No additional information available

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not determined

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

Not determined

15.2.2. National regulations

No additional information available

15.3. US State regulations

Not determined

SECTION 16: Other information

References : Available upon request

Other information : None.

Full text of H-phrases: see sections 2 & 3:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Asp. Tox. 1	Aspiration hazard Category 1
Carc. 2	Carcinogenicity Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Repr. 1A	Reproductive toxicity Category 1A
Skin Sens. 1	Skin sensitization Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H301	Toxic if swallowed
H304	May be fatal if swallowed and enters airways
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H335	May cause respiratory irritation

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H336	May cause drowsiness or dizziness
H351	Suspected of causing cancer
H360	May damage fertility or the unborn child

SDS US (GHS HazCom 2012)

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material in an industrial setting. It is not meant to be an all-inclusive document on worldwide hazard communication regulations. This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate mechanisms to prevent employee exposures, property damage or release to the environment. Refer to Product Monograph for pharmaceutical use information.



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SAFETY DATA SHEET

Section 1. Product And Company Identification

Product Name: EMPOWER™
Product Use: Instrument Cleaner

Manufacturer: METREX™ RESEARCH
1717 W. Collins Ave.
Orange, CA 92867
U.S.A.

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

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

SDS Date Of Preparation/Revision: 12/8/14

Section 2. Hazards Identification

GHS / HAZCOM 2012 Classification:
Respiratory Sensitization Category 1

Label Elements

Danger!



Avoid breathing mist, vapors or spray.
In case of inadequate ventilation wear respiratory protection.
IF INHALED: remove person to fresh air and keep comfortable for breathing.
If experiencing respiratory symptoms: Call a POISON CENTER.
Dispose of contents and container in accordance with local and national regulations.

Section 3. Composition/Information On Ingredients

Component	CAS No.	Amount
Water and non-hazardous ingredients	Mixture	60-85%
Propylene glycol	57-55-6	10-30%
Trisodium Citrate Dihydrate	68-04-2	5-10%
Proteinase subtilisin	9014-01	0.1-<1%



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Section 4. First Aid Measures

Eye Contact: Hold eye open and rinse slowly and gently with water for 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Seek medical attention if irritation develops and persists.

Skin Contact: Wash with soap and water. Seek medical attention if irritation develops and persists. Remove and launder contaminated clothing.

Inhalation: Move to fresh air. If respiratory symptoms occur, get medical attention.

Ingestion: If the victim is alert, have them rinse their mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Do not attempt to give anything by mouth to an unconscious person. Seek medical advice by calling a Poison Center or doctor.

Most important symptoms and effects, acute and delayed: May cause eye and skin irritation. Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract. Inhalation of mists may cause an allergic reaction, particularly in sensitized individuals.

Indication of immediate medical attention and special treatment, if needed: Treat symptomatically.

Section 5. Fire Fighting Measures

Suitable (and Unsuitable) Extinguishing Media: Use any extinguishing media that is appropriate for the surrounding fire. Cool fire exposed containers with water.

Specific Hazards Arising from the Chemical: None known.

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

Section 6: Accidental Release Measures

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

Methods and Materials for Containment and Cleaning up: Collect material with an inert absorbent material and place in appropriate, labeled container for disposal.

Section 7. Handling and Storage

Precautions for Safe Handling: Avoid contact with eyes, skin and clothing. Avoid generating and breathing mists. Wear appropriate eye protection when handling. Wash thoroughly with soap and water



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after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Conditions for Safe Storage, Including any Incompatibilities: Store at room temperature.

Section 8. Exposure Controls / Personal Protection

Exposure Limits

Chemical	Exposure Limit
Propylene glycol	10 mg/m ³ TWA AIHA WEEL
Trisodium Citrate Dihydrate	None Established
Proteinase subtilisin	0.00006 mg/m ³ (as 100% crystalline active pure enzyme) TWA ACGIH Ceiling Limit

Appropriate Engineering Controls: General ventilation should be adequate for normal use. For operations where the exposures are excessive, mechanical ventilation such as local exhaust may be needed to minimize exposure.

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

Hand protection: Impervious gloves such as butyl rubber or nitrile are recommended.

Eye Protection: Safety goggles are recommended if needed to prevent eye contact.

Skin Protection: Wear protective clothing if needed to avoid prolonged/ repeated skin contact.

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

Section 9. Physical and Chemical Properties

Appearance:	Clear blue liquid.	Odor:	Coastal Breeze Scent
Odor Threshold:	Not determined	pH:	7.5-8.5
Melting/Freezing Point:	Not determined	Boiling Point/Range:	100-105°C
Flash Point:	Not flammable	Evaporation Rate:	<1
Flammability: (Solid, Gas)	Not applicable	Flammability Limits:	Not applicable
Vapor Pressure:	Same as water	Vapor Density:	Same as water
Relative Density:	>1.07	Solubilities:	Completely soluble
Partition Coefficient: (N-Octanol/Water)	Not determined	Autoignition Temperature:	Not determined
Decomposition Temperature:	Not determined		



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Section 10. Stability and Reactivity

Reactivity: Not reactive at ambient temperatures.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: Not reactive.

Conditions to avoid: Avoid excessive heat.

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

Hazardous decomposition products: Thermal decomposition will produce carbon monoxide, carbon dioxide, nitrogen oxides, and hydrocarbons.

Section 11. Toxicological Information

Potential Health Effects:

Inhalation: May cause minor irritation of the nose, throat and upper respiratory tract. Inhalation of mists may cause an allergic reaction in individuals sensitized to enzymes.

Skin Contact: Prolonged or repeated exposure may cause mild irritation.

Eye Contact: May cause irritation with tearing, redness and pain.

Ingestion: Ingestion may cause gastrointestinal disturbances.

Chronic Hazards: None currently known.

Sensitization: Inhalation studies with guinea pigs showed proteinase subtilisin caused respiratory sensitization.

Mutagenicity: None of the components have been shown to cause mutagenic activity.

Developmental / Reproductive Toxicity: This product is not expected to cause adverse reproductive or developmental effects.

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

Acute Toxicity Values:

Propylene Glycol: LD50 Oral Rat 20,000 – 34,000 mg/kg; LD50 Dermal Rabbit >20,000 mg/kg

Trisodium Citrate Dihydrate: No data available.

Proteinase subtilisin: LD50 Oral Rat 1800 mg/kg

Section 12. Ecological Information

Toxicity: No toxicity data available for product.

Propylene Glycol: 96 hr LC50 *Oncorhynchus mykiss* 40613 mg/L, 48 hr *Ceriodaphnia dubia* 18340 mg/L, 72 hr EC50 algae 19300 mg/L

Trisodium Citrate Dihydrate: Not toxicity data available

Proteinase subtilisin: 96 hr LC50 *Oncorhynchus mykiss* 14.6 mg/L, 48 hr LC50 *daphnia magna* 0.306 mg/L, 72 hr EC50 algae 830 µg/L.



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Persistence and degradability: Propylene glycol and Proteinase subtilisin are readily biodegradable. Trisodium Citrate Dihydrate is inherently biodegradable.

Bioaccumulative Potential: Propylene glycol and trisodium citrate dehydrate have a BCF of <1.

Mobility in Soil: No data available for product.

Other Adverse Effects: None known

Section 13. Disposal Considerations

Solution Disposal: For unused solution, flush thoroughly with large quantities of water into sewage disposal system in accordance with Federal, State, and local regulations. For used solution, the waste solution must be characterized by the generator and disposed of in accordance with Federal, State, and local regulations.

Container Disposal: Do not reuse empty container. Wrap container and put in trash.

Section 14. Transport Information

	UN Number	UN Proper Shipping Name	Hazard Class(s)	Packing Group	Environmental Hazards
U.S. DOT	None	Not Regulated			None
Canada TDG	None	Not Regulated			None
IMDG	None	Not Regulated			None
IATA/ICAO	None	Not Regulated			None

Section 15. Regulatory Information

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

EPA SARA 313: This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

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

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

Canadian Regulations

National Pollutant Release Inventory (NPRI): This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements NPRI: None

WHMIS Classification: Class D-2-A

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.



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International Inventories

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

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

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

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

New Zealand: All of the components in this product are listed on the New Zealand Inventory of Chemicals (NZIoC) or exempt.

Section 16. Other Information

NFPA Rating: Fire: 0

Health: 2

Instability: 0

Effective Date: 12/8/14

Supersedes Date: New SDS

Revision Summary: New SDS

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



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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

Hospira UK Limited

Horizon
 Honey Lane
 Hurley
 Maidenhead, SL6 6RJ
 United Kingdom

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

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

Note:

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Epinephrine	51-43-4	200-098-7	Acute Tox. 2 (H300) Acute Tox. 2 (H310)	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

None known

Aggravated by Exposure:**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.

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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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia PEAK	5 ppm 7.5 mg/m ³
Austria OEL - MAKs	5 ppm 8 mg/m ³
Belgium OEL - TWA	5 ppm 8 mg/m ³
Bulgaria OEL - TWA	5 ppm 8.0 mg/m ³
Cyprus OEL - TWA	5 ppm 8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³
Estonia OEL - TWA	5 ppm 8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m ³
Germany (DFG) - MAK	2 ppm 3.0 mg/m ³
Greece OEL - TWA	5 ppm 7 mg/m ³
Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm 8 mg/m ³
Italy OEL - TWA	5 ppm 8 mg/m ³
Japan - OELs - Ceilings	2 ppm 3.0 mg/m ³
Latvia OEL - TWA	5 ppm 8 mg/m ³
Lithuania OEL - TWA	5 ppm 8 mg/m ³
Luxembourg OEL - TWA	5 ppm 8 mg/m ³
Malta OEL - TWA	5 ppm 8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 ppm 8 mg/m ³
Romania OEL - TWA	5 ppm 8 mg/m ³
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	5 ppm 8 mg/m ³
Spain OEL - TWA	5 ppm 7.6 mg/m ³
Switzerland OEL - TWAs	2 ppm 3.0 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³
Sodium chloride	
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Epinephrine

Pfizer Occupational Exposure Band (OEB): OEB 4 - Skin (control exposure to the range of 1ug/m³ to <10ug/m³, provide additional precautions to protect from skin contact)

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
Odor: No data available.
Molecular Formula: Mixture

Color: Clear colorless
Odor Threshold: No data available.
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.

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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

Flammability:

Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

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

General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: May be absorbed through the skin and cause systemic effects. 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**

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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)	<i>Salmonella</i>	Negative
Sister Chromatid Exchange	Negative with activation	
Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Equivocal without activation

HYDROCHLORIC ACID

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vivo</i> 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

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13. DISPOSAL CONSIDERATIONS

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

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

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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
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	231-595-7

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.

SAFETY DATA SHEET

Material Name: Epinephrine Injection (Hospira, Inc.)
Revision date: 03-Nov-2016

Page 10 of 10
Version: 1.0

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



United Exchange Corp.
17211 Valley View Ave.,
Cerritos, CA 90703

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name/Trade Name: Antiseptic Cleansing wipes item # 90126

Supplier: United Exchange Corp.

17211 Valley View Ave.,

Cerritos, CA 90703 USA

Information Phone: 562-977-4500

2. SPECIFICATION OF MATERIAL AND QUANTITY

USE: skin disinfection and wound disinfection

Material Name	Chemistry name	Contain (%)
benzalkonium bromide	benzalkonium bromide	0.5%

3. HAZARDS IDENTIFICATION

EYE CONTACT: Maybe irritant to eyes.

4. FIRST AID MEASURES

EYE CONTACT: Rinse the eyes thoroughly with clean water for at least 15 minutes, lifting the eyelids and rotating the eye during the rinsing. If irritation persists, consult a physician

SKIN CONTACT: Rinse skin thoroughly with water for at least 15 minutes.

INGESTION: Consult a physician and/or poison control center right away.

INHALATION: If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Consult a physician and/or poison control center.

5. FIRE FIGHTING

FLASH POINT (METHOD USED): NA

EXTINGUISHING MEDIA: Water spray, dry chemical powder, appropriate foam or carbon dioxide.

6. ACCIDENTAL RELEASE MEASURES

PROCEDURES OF PERSONAL PRECAUTIONS: Wear appropriate clothing.



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METHOD FOR CLEANING UP: Mix with inert material (e.g. dry sand, vermiculite) and transfer to a dry, clean, lidded container for disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.

7. HANDLING AND STORAGE

USER EXPOSURE: Avoid contact with eyes.

INCOMPATIBILITIES: Strong oxidizing agents.

STORAGE: Store in a cool, well-ventilated area. Keep away from ignition sources, heat and flame. Store in a tightly closed container.

8. EXPOSURE CONTROLS/PPE

ENGINEERING CONTROLS: eye bath. Mechanical exhaust not required.

PERSONAL PROTECTIVE EQUIPMENT:

Respiratory protection: Not required.

Eye protection: Use safety glasses if needed.

Protective gloves: Not required.

Other protective equipment: Not required.

Work practice: Good hygienic practice. No smoking, drinking or eating at working site.

9. PHYSICAL AND CHEMICAL PROPERTIES (Lotion)

SOLUBILITY IN WATER: Soluble PH: 4~8

APPEARANCE & ODOR: Clear/Slight yellow liquid with characteristic odor.

10. STABILITY AND REACTIVITY

STABILITY: Stable.

CONDITIONS TO AVOID: Excessively high storage temperatures and strong oxidizing agents.

HAZARDOUS POLYMERIZATION: Will not occur.

DECOMPOSITION PRODUCTS: Thermal/oxidative decomposition can yield carbon monoxide, carbon dioxide, nitrogen oxides and other complex organic breakdown products.

11. ECOLOGICAL INFORMATION

Information not available.

12. DISPOSAL CONSIDERATIONS



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Any disposal practice must be in compliance with local and national laws and regulations. Contact the appropriate agency for specific information. Treatment, transport, storage and disposal of hazardous waste must be carried out by a licensed facility or waste hauler.

13. TRANSPORT INFORMATION

D.O.T. :

Proper Shipping Name: None.

Non-Hazardous for Transport: This substance is considered to be non-hazardous for transport.

IATA:

Non-Hazardous for Air Transport: Non-hazardous for air transport.

IMO:

Non-Hazardous for Sea Transport: Non-hazardous for sea transport.

14. REGULATORY INFORMATION

This product is regulated by FDA. Product listing with FDA is required before production taken place.

The data here is for hazard communication to our employees, our customers and their employees, and authorized regulatory agencies. For the intended purpose, this MSDS (Material Safety data Sheet) may be duplicated or the data transcribed to an alternative form.

NOTE: The information contained herein is provided in good faith and is believe to be correct as of the date hereof. However, United Exchange Corp. makes no representation as to the comprehensiveness or accuracy of the information. It is expected that individuals receiving the information will exercise their independent judgment in determining its appropriateness for a particular period. Accordingly United Exchange Corp. will not be responsible for damages of any kind resulting from the use of or reliance upon such information. NO REPRESENTATIONS, OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER NATURE ARE MADE HEREUNDER TO WHICH THE INFORMATION REFERS. The responsibility to provide a safe workplace remains with the user. The user should consider the health hazards and safety information contained herein as a guide and should take those precautions required in an individual operation to instruct employees and develop work practice procedures for a safe work environment.

Safety Data Sheet

according to 29CFR1910/1200 and GHS Rev. 3

Effective date : 01.08.2015

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EZ-Kill Disinfecting/Deodorizing/Cleaning Wipes

SECTION 1 : Identification of the substance/mixture and of the supplier**Product name :** EZ-Kill Disinfecting/Deodorizing/Cleaning Wipes**Manufacturer/Supplier Trade name:** EZ-Kill Disinfecting/Deodorizing/Cleaning Wipes**Manufacturer/Supplier Article number:** EZ-Kill Disinfecting/Deodorizing/Cleaning Wipes**Recommended uses of the product and uses restrictions on use:** Hard surface cleaner and disinfecting wipes specially formulated with a solution which is safe to use on hard surfaces.No significant hazards will arise from the intended and correct use of this product. See product label or insert for intended uses.**Manufacturer Details:**

HealthLink

3611 St. Johns Bluff Road

Jacksonville Florida, 32224

For technical information: 1.800.638.2625

Emergency telephone number:

Chemtrec 1.800.424.9300

SECTION 2 : Hazards identification**Classification of the substance or mixture:****Flammable**

Flammable solid, category 3

Flammable Solid 3

Signal word :Warning**Hazard statements:**

Flammable liquid and vapor

Precautionary statements:

If medical advice is needed, have product container or label at hand

Read label before use

Keep container tightly closed

Use explosion-proof electrical/ventilating/light/equipment

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

Ground/bond container and receiving equipment

Use only non-sparking tools

Take precautionary measures against static discharge

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

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

In case of fire: Use agents recommended in section 5 for extinction

Store in a well ventilated place. Keep container tightly closed

Dispose of contents and container as instructed in Section 13

Other Non-GHS Classification:

WHMIS

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EZ-Kill Disinfecting/Deodorizing/Cleaning Wipes

**NFPA/HMIS**

NFPA SCALE (0-4)

Health	1
Flammability	2
Physical Hazard	0
Personal Protection	X

HMIS RATINGS (0-4)

SECTION 3 : Composition/information on ingredients

Ingredients:		
CAS 67-63-0	Isopropanol	41.58 %
CAS Trade Secret	Glycol Ether	1-5 %
CAS Trade Secret	Aliphatic Polymer	1-5 %
CAS 68391-01-5	Alkyl (C12,C14,C16) Dimethyl Benzyl Ammonium Chloride	0.12 %
CAS 85409-23-0	Alkyl Dimethyl Ethyl Benzyl Ammonium Chloride	0.12 %
Percentages are by weight		

SECTION 4 : First aid measures**Description of first aid measures**

After inhalation: Move exposed individual to fresh air. Loosen clothing as necessary and position individual in a comfortable position. Seek medical advice if discomfort or irritation persists.

After skin contact: Wash affected area with soap and water. Rinse/flush exposed skin gently using water for 15-20 minutes. Seek medical attention if irritation persists or if concerned.

After eye contact: Protect unexposed eye. Immediately flush eyes with water for at least 15 minutes. Immediately get medical assistance.

After swallowing: Dilute mouth with water or milk after rinsing. Immediately get medical assistance. Induce vomiting if directed to do so by medical personnel.

Most important symptoms and effects, both acute and delayed:

Shortness of breath. Irritation. Nausea. Headache.;

Indication of any immediate medical attention and special treatment needed:

If seeking medical attention, provide SDS document to physician. Physician should treat symptomatically.

SECTION 5 : Firefighting measures

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	EZ-Kill Disinfecting/Deodorizing/Cleaning Wipes	

Extinguishing media

Suitable extinguishing agents: Use water, dry chemical, chemical foam, carbon dioxide, or alcohol-resistant foam. Water spray can be used to dilute spills to nonflammable mixtures.

For safety reasons unsuitable extinguishing agents:

Special hazards arising from the substance or mixture:

Advice for firefighters:

Protective equipment: Wear protective eyewear, gloves, and clothing. Refer to Section 8.

Additional information (precautions): Ensure adequate ventilation. Avoid contact with skin, eyes, and clothing. Do not inhale gases, fumes, dust, mist, vapor, and aerosols.

SECTION 6 : Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Keep away from ignition sources. Protect from heat. Ensure that dust-handling systems (exhaust ducts, dust collectors, vessels, and processing equipment) are designed to prevent the escape of dust into the work area.

Environmental precautions:

Prevent from reaching drains, sewer or waterway. Should not be released into environment.

Methods and material for containment and cleaning up:

Use spark-proof tools and explosion-proof equipment. Have fire extinguishing agent available in case of fire. Always obey local regulations. Collect liquids using vacuum or by use of absorbents. Place into properly labeled containers for recovery or disposal. Remove all sources of ignition. Contain spill then collect. Do not flush to sewer. Absorb with a noncombustible absorbent material such as sand or earth and containerize for disposal. Refer to Section 13. Ventilate area of spill.

Reference to other sections:

SECTION 7 : Handling and storage

Precautions for safe handling:

Do not eat, drink, smoke, or use personal products when handling chemical substances. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes, and clothing. Empty containers retain product residue and can be dangerous.

Conditions for safe storage, including any incompatibilities:

Store in a cool location. Store securely in flammable storage area away from sources of ignition. Provide ventilation for containers. Avoid storage near extreme heat, ignition sources or open flame. Keep container tightly sealed. Protect from freezing and physical damage. Store away from incompatible materials.

SECTION 8 : Exposure controls/personal protection



Control Parameters:

67-63-0, Isopropanol, ACGIH: 400 ppm STEL; 200 ppm TWA
 67-63-0, Isopropanol, NIOSH: 500 ppm STEL; 1225 mg/m³ STEL
 67-63-0, Isopropanol, NIOSH: 400 ppm TWA; 980 mg/m³ TWA

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	EZ-Kill Disinfecting/Deodorizing/Cleaning Wipes	

Appropriate Engineering controls:	Emergency eye wash fountains and safety showers should be available in the immediate vicinity of use or handling. Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapor and mists below the applicable workplace exposure limits (Occupational Exposure Limits-OELs) indicated above.
Respiratory protection:	Not required under normal conditions of use. Use suitable respiratory protective device when high concentrations are present.
Protection of skin:	Select glove material impermeable and resistant to the substance. Select glove material based on rates of diffusion and degradation.
Eye protection:	Safety glasses with side shields or goggles.
General hygienic measures:	Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin. Perform routine housekeeping. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

SECTION 9 : Physical and chemical properties

Appearance (physical state,color):	Clear colorless liquid	Explosion limit lower:	2%
		Explosion limit upper:	12.7%
Odor:	Alcohol	Vapor pressure:	Approx 33 at 20°C
Odor threshold:	Not Available	Vapor density:	Not Available
pH-value:	Not Available	Relative density:	0.88 g/mL at 25°C
Melting/Freezing point:	Below -88°C	Solubilities:	Infinite solubility
Boiling point/Boiling range:	Approx 82°C	Partition coefficient (n-octanol/water):	log Pow: 0.05
Flash point (closed cup):	82F/27C	Auto/Self-ignition temperature:	425.0°C
Evaporation rate:	3.0	Decomposition temperature:	Not Available
Flammability (solid,gaseous):	Flammable	Viscosity:	a. Kinematic: Not Available b. Dynamic: Not Available
Density: Not Available			

SECTION 10 : Stability and reactivity**Reactivity:**None under normal processing. Test small inconspicuous area.**Chemical stability:**No decomposition if used and stored according to specifications. Stable under normal conditions.**Possible hazardous reactions:**Flammable. Used empty containers may contain product gases which form explosive mixtures with air. Can form explosive mixtures in air if heated above flash point and/or when sprayed or atomised.**Conditions to avoid:**Incompatible materials.**Incompatible materials:**Strong oxidizers, heat, sparks, open flames. Will attack some forms of rubber, plastics and coatings. May react with metallic aluminum and generate hydrogen gas.**Hazardous decomposition products:**Toxic oxides of carbon, acrid and irritating fumes.**SECTION 11 : Toxicological information**

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EZ-Kill Disinfecting/Deodorizing/Cleaning Wipes

Acute Toxicity:		
Oral:	67-63-0	LD50 Rat - 5,045 mg/kg
Inhalation:	67-63-0	LC50- Rat - 8 h - 16000 ppm
Dermal:	67-63-0	LD50 - Rabbit - 12,800 mg/kg
Chronic Toxicity: No additional information.		
Corrosion Irritation: No additional information.		
Sensitization:		No additional information.
Single Target Organ (STOT):		No additional information.
Numerical Measures:		No additional information.
Carcinogenicity:		No additional information.
Mutagenicity:		No additional information.
Reproductive Toxicity:		No additional information.

SECTION 12 : Ecological information**Ecotoxicity**

Toxicity to fish LC50 - Pimephales promelas (fathead minnow) - 9,640.00 mg/l - 96 h: 67-63-0

Toxicity to daphnia and other aquatic invertebrates EC50 - Daphnia magna (Water flea) - 5,102.00 mg/l - 24 h: 67-63-0

Toxicity to algae EC50 - Desmodesmus subspicatus (green algae) - > 2,000.00 mg/l - 72 h EC50 - Algae - > 1,000.00 mg/l - 24 h: 67-63-0

Persistence and degradability:**Bioaccumulative potential:**

Mobility in soil: Aqueous solution has high mobility in soil.

Other adverse effects: Isopropanol has acute toxicity with effects of death in animals and low growth rates and death in plants. Chronic toxic effects, may be shortened life span, lower fertility, reproductive problems, and changes in appearance and/or behavior in animals

SECTION 13 : Disposal considerations**Waste disposal recommendations:**

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory entities (US 40CFR262.11). Remove all sources of ignition. Do not flush to sewer. Have fire extinguishing agent available in case of fire. Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations. Ensure complete and accurate classification.

SECTION 14 : Transport information**UN-Number**

Limited Quantity

UN proper shipping name

Ltd Qty, Ground Transportation

Class 55 Cleaning Compound wipes

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EZ-Kill Disinfecting/Deodorizing/Cleaning Wipes

Transport hazard class(es)**Packing group:**None**Environmental hazard:****Transport in bulk:****Special precautions for user:****SECTION 15 : Regulatory information****United States (USA)****SARA Section 311/312 (Specific toxic chemical listings):**

Acute, Chronic, Fire

SARA Section 313 (Specific toxic chemical listings):

67-63-0 Isopropanol

RCRA (hazardous waste code):

None of the ingredients is listed

TSCA (Toxic Substances Control Act):

All ingredients are listed.

CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act):

None of the ingredients is listed

Proposition 65 (California):**Chemicals known to cause cancer:**

None of the ingredients is listed

Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed

Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed

Chemicals known to cause developmental toxicity:

None of the ingredients is listed

Canada**Canadian Domestic Substances List (DSL):**

All ingredients are listed.

Canadian NPRI Ingredient Disclosure list (limit 0.1%):

None of the ingredients is listed

Canadian NPRI Ingredient Disclosure list (limit 1%):

67-63-0 Isopropanol

SECTION 16 : Other information

This product has been classified in accordance with hazard criteria of the Controlled Products Regulations and the SDS contains all the information required by the Controlled Products Regulations. Note: The responsibility to provide a safe workplace remains with the user. The user should consider the health hazards and safety information contained herein as a guide and should take those precautions required in an individual operation to instruct employees and develop work practice procedures for a safe work environment. The information contained herein is,

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EZ-Kill Disinfecting/Deodorizing/Cleaning Wipes

to the best of our knowledge and belief, accurate. However, since the conditions of handling and use are beyond our control, we make no guarantee of results, and assume no liability for damages incurred by the use of this material. It is the responsibility of the user to comply with all applicable laws and regulations applicable to this material.

This chemical is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use.

KEEP OUT OF REACH OF CHILDREN.

WARNING - PRECAUTIONARY STATEMENTS: Hazard to Humans and Domestic Animals.

WARNING: Causes substantial but temporary eye injury.

GHS Full Text Phrases:**Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

PNEC: Predicted No-Effect Concentration (REACH)

CFR: Code of Federal Regulations (USA)

SARA: Superfund Amendments and Reauthorization Act (USA)

RCRA: Resource Conservation and Recovery Act (USA)

TSCA: Toxic Substances Control Act (USA)

NPRI: National Pollutant Release Inventory (Canada)

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

WHMIS: Workplace Hazardous Materials Information System (Canada)

DNEL: Derived No-Effect Level (REACH)

Effective date : 01.08.2015

Last updated : 05.05.2015 SL107



SDS: Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP

SAFETY DATA SHEET

1. Identification

Product Identifier:	Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP 0.6 mg Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP 1.0 mg
Synonyms:	Ful-Glo®, Fluorescein sodium; Acid Yellow 73; Uranine; FD&C yellow 8; CI acid yellow 73; Spiro[isobenzofuran-1(3H), 9'-[9H]xanthen]-3-one, 3',6'-dihydroxy-, disodium salt; C.I. 45350
National Drug Code (NDC):	17478-403-03 17478-404-01
Recommended Use:	Pharmaceutical.
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 classifiable.
Health Hazards:	Not classifiable.
Symbol(s):	None.
Signal Word:	None.
Hazard Statement(s):	None.
Precautionary Statement(s):	None.
Hazards Not Otherwise Classified:	Not classifiable.
Supplementary Information:	While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product. Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention.



SDS: Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Spiro[isobenzofuran-1(3H), 9'-[9H]xanthen]-3-one, 3',6'-dihydroxy-, disodium salt	518-47-8	Fluorescein Sodium; Acid Yellow 73; Uranine; FD&C Yellow 8; CI Acid Yellow 73; C.I. 45350	$C_{20}H_{10}O_5 \cdot Na_2$	376.27	100%*

* *Each sterile strip is impregnated with Fluorescein Sodium:

NDC 17478-403-03: Fluorescein Sodium, 0.6 mg;
NDC 17478-404-01: Fluorescein Sodium, 1.0 mg.

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:

No data available.



SDS: Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP

Medical Conditions Aggravated by Exposure: May aggravate allergies and bronchial asthma.

Notes to Physician: Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media: Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: These products include carbon oxides and sodium oxides.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment/Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Dike ahead of liquid spills for later disposal. 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: Store according to label and/or product insert information. Store away from oxidizers, acids, and bases.

Specific End Use: Pharmaceuticals.



SDS: Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Fluorescein sodium	No data available.

Engineering Controls:	Engineering controls should be used as the primary means to control exposures.
Respiratory Protection:	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:	Safety glasses with side shields are recommended. 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:	Chemically compatible gloves. 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:	Protective laboratory coat, apron, or disposable garment.

9. Physical and Chemical Properties

Physical State/Color:	Solid strips/Red-orange tip.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	No data available.
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):	No data available.
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):	Miscible in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.



SDS: Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP

Decomposition Temperature: No data available.
Viscosity: No data available.

10. Stability and Reactivity

Reactivity: No data available.
Chemical Stability: Stable under recommended storage conditions.
Possibility of Hazardous Reactions: No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration): No data available.
Incompatible Materials: Oxidizers, acids, and bases.
Hazardous Decomposition Products: No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion: May be harmful if swallowed.
Skin Contact: May be harmful if absorbed through the skin. May cause yellowish discoloration. May cause irritation.
Eye Contact: May cause eye irritation.

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:

Hives, itching, bronchospasm, and anaphylaxis have been reported. Syncope and hypotension may occur. Cardiac arrest, basilar artery ischemia, severe shock and death may occur rarely.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Fluorescein Sodium	Rat	Oral	LD ₅₀	6,721 mg/kg

Acute Toxicity – Dermal: No data available.
Acute Toxicity – Inhalation: No data available.
Corrosivity: No data available.
Dermal Irritation: No data available.
Eye Irritation: No data available.
Sensitization: No data available.
Toxicokinetics/Metabolism: No data available.



SDS: Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP

Target Organ Effects:	No data available.
Reproductive Effects:	No data available.
Carcinogenicity:	No data available.
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.
Mutagenicity:	No data available.
Aspiration Hazard:	No data available.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
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

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA):	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.



SDS: Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

Massachusetts: Not listed.
New Jersey: Not listed.
Pennsylvania: Not listed.
California Proposition 65: Not listed.

16. Other Information

NFPA Rating:	HMIS Classification:
Health: 0	Health: 0
Flammability: 0	Flammability: 0
Reactivity: 0	Physical Hazard: 0

Revision Date: 06/29/2015

Revision Number: 2

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 (SDS)

Section 1: IDENTIFICATION				
TRADE NAME	Gebauer's Pain Ease®	MANUFACTURER	Gebauer Company 4444 East 153 Street Cleveland, Ohio 44128	
CHEMICAL NAME	1,1,1,3,3-Pentafluoropropane 1,1,1,2-Tetrafluoroethane	CONTACT INFORMATION	Toll Free: (800) 321-9348 Phone: (216) 581-3030 Fax: (216) 581-4970	
RECOMMENDED USE	Topical Anesthetic	IN CASE OF EMERGENCY	CHEMTREC - (800) 242-9300 or (703) 527-3887	
FORMULA	CHF ₂ CH ₂ CF ₃ / CH ₂ FCF ₃	CHEMICAL FAMILY	Halogenated Hydrocarbon	
Section 2: HAZARDS IDENTIFICATION				
		Health Rating	2 - Moderate	
		Flammability Rating	0 - None	
		Reactivity Rating	1 - Moderate	
		Special Rating	None	
		Lab Protective Equipment	Neoprene or Viton gloves, lab coat, goggles or face shield, vent hood.	
Hazard Category	Signal Word	Hazard Statement	Pictogram	Precautionary Statement
Compressed Gas	Warning	Contains gas under pressure; may explode if heated		Store in a well-ventilated place.
Eye Irritation (Category 2B)	Warning	Causes eye irritation	N/A	If product gets into eyes, see the Section 4: First Aid Measures.
Cause		Effects		
Potential Acute Health Effects	Inhalation	When oxygen levels in air are reduced to 12-14% by displacement, symptoms of asphyxiation, loss of coordination, increased pulse rate and deeper respiration will occur. At high levels, cardiac arrhythmia may occur.		
	Ingestion	Unlikely route of exposure due to gaseous nature. Discomfort due to volatility would be expected.		
	Eye Contact	Liquid contact can cause irritation and frostbite.		
	Skin Contact	Over application could cause frostbite. Liquid contact is non-irritating.		
Section 3: COMPOSITION / INFORMATION ON INGREDIENTS				
Ingredient	CAS Number	Concentration	OSHA PEL	ACGIH TLV-TWA
1,1,1,3,3-Pentafluoropropane	460-73-1	95%	None	None
1,1,1,2-Tetrafluoroethane	811-97-1	5%	None	None
Section 4: FIRST AID MEASURES				
Inhalation	Immediately remove patient to fresh air. If breathing has stopped, give artificial respiration. Use oxygen as required, provided a qualified operator is available. DO NOT give epinephrine (adrenaline). Get medical attention immediately.			
Ingestion	Unlikely route of exposure due to gaseous nature. DO NOT induce vomiting unless instructed to do so by a physician. DO NOT give stimulants. Get medical attention immediately.			
Skin Contact	If there is evidence of frostbite seek medical attention.			
Eye Contact	Immediately flush eyes with copious amounts of water for at least 15 minutes (in case of frostbite water should be lukewarm, not hot) lifting lids occasionally to facilitate irrigation. Get medical attention.			
Section 5: FIRE FIGHTING MEASURES				
Special Fire Fighting Procedures Fire fighters should wear self-contained, NIOSH approved breathing apparatus for protection against possible toxic decomposition products. Proper eye and skin protection should be provided. Use spray to keep fire-exposed containers cool.				
Unusual Fire and Explosion Hazards Not flammable at ambient temperatures and atmospheric pressure. However this material will become combustible when mixed with air under pressure and exposed to strong ignition sources contact with certain reactive metals may result in formation of explosive or exothermic reactions under specific conditions (e.g. very high temperatures and/or appropriate pressures).				
Section 6: ACCIDENTAL RELEASE MEASURES				
Spill and Leak Response If a large quantity of containers the product has been released, evacuate unprotected personnel. Protected personnel should eliminate all sources of ignition and shut off leak, if without risk, and provide ventilation.				
Waste Disposal Method Comply with federal, state and local laws.				

Section 7: HANDLING AND STORAGE

Storage Precautions

Store in cool, dry, well ventilated area of low fire risk. Protect against physical damage. Do not subject to temperatures above 120°F (50°C).

Handling Precautions

Use in well-ventilated areas. Do not use near temperatures above 120°F (50°C).

Section 8: EXPOSURE CONTROLS – PERSONAL PROTECTION

Engineering Controls

Provide local ventilation at filling zones and where leakage is probable. Use with adequate ventilation.

Respiratory Protection

None generally required for adequately ventilated work situations. For accidental release in confined space, where the concentration may be above the PEL of 1,000 ppm, use a NIOSH approved, self contained, positive pressure respirator for emergencies and in situations where air may be displaced by vapors.

Skin Protection

Use protective, impervious gloves and clothing made of neoprene, nitrile or butyl rubber if prolonged or repeated contact with liquid is anticipated. Wash clothing promptly, if wet. Remove any non-impervious clothing and wash before re-use.

Eye Protection

For normal conditions, wear safety glasses. Where there is reasonable probability of liquid contact, wear splash-proof goggles. Contact lenses should not be worn under such conditions.

Exposure Limits

OSHA PEL: None ACGIH TLV: None

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point: 44.6°F (7.0°C)

Evaporation Rate:
(Carbon Tetrachloride = 1) >1

Vapor Density: Air=1 BP 4.7

Vapor Pressure (@72°F): 10.8 psig

Specific Gravity (@72°F): 1.33

Appearance: Colorless Liquid

Flash Point: None

Flammable Limits in Air:
(by Volume) Nonflammable

Odor: Faint Ethereal, Sweet

Section 10: STABILITY AND REACTIVITY

Stability

Product is stable under normal conditions.

Hazardous Decomposition Products

Halogens and halogen acids; and possibly carbonyl halides.

Incompatible Materials

Strong acids and alkalis, reactive metals e.g., powdered or freshly abraded aluminum (may cause strong exothermic reaction), sodium, potassium, calcium, magnesium, zinc, molten aluminum, barium and lithium shavings. Strong oxidizing agents.

Hazardous Polymerization

Does not occur.

Conditions to Avoid

Avoid sources of ignition such as sparks, hot spots, welding flames and lighted cigarettes which may yield toxic and/or corrosive decomposition products. Do not mix with oxygen or air above atmospheric pressure.

Section 11: TOXICOLOGICAL INFORMATION

Dermal Irritation

Non-irritation and not a skin sensitizer.

Eye Irritation

Very slight irritant.

Inhalation

Evidence of transient anesthetic effect. 1,1,1,2-Tetrafluoroethane: Lowest observed adverse effect level for cardiac sensitization was 75,000ppm.

Section 12: ECOLOGICAL INFORMATION

Environmental Stability

Gas is dissipated rapidly in a ventilated area.

Effect on Aquatic Life

CAS 40-73-1: Acute Toxicity to Rainbow Trout (Limit Test): NOEC >10 mg/L; 96 hr. EC₅₀>8108 mg/L
CAS 811-97-1: Acute Toxicity to Rainbow Trout (Limit Test): 96 hr. LC₅₀ is 450 mg/L

Section 13: DISPOSAL CONSIDERATIONS

Waste disposal must be in accordance with appropriate Federal, State and local regulations.

Section 14: TRANSPORT INFORMATION

DOT

UN Number

UN 3163

Proper Shipping Name

Liquefied Gas, N.O.S (1,1,1,3,3-Pentafluoropropane, 1,1,1,2-Tetrafluoroethane)

Class

2.2, Non-Flammable Gas

Hazard Label

Limited Quantities

IATA

UN Number

UN 3163

Proper Shipping Name

Liquefied Gas, N.O.S (1,1,1,3,3-Pentafluoropropane, 1,1,1,2-Tetrafluoroethane)

Class

2.2, Non-Flammable Gas

Hazard Label

Air-Specific Limited Quantities

Section 15: REGULATORY INFORMATION

USA TSCA

Not Listed

Europe EINECS

Not Listed

SARA Title III

RQ's and EHS TPQ: Not Listed. Sections 311, 312: Not Listed

WHMIS Classification (Canada)

SDS meets requirements of SPR

European Union

Not Listed as Hazardous Substance

Additional Regulatory Information

Contains greenhouse gases, which may contribute to global warming. Regulated in the US under Section 612 (SNAP) of the Clean Air Act and 40 CFR Part 82, subpart G.

Section 16: OTHER INFORMATION

This SDS was revised and updated as of 08/20/2013 by Gebauer Company.

INFORMATION CONTAINED IN THIS SAFETY DATA SHEET IS OFFERED WITHOUT CHARGE FOR USE BY TECHNICALLY QUALIFIED PERSONNEL AT THEIR DISCRETION AND RISK. ALL STATEMENTS, TECHNICAL INFORMATION AND RECOMMENDATIONS CONTAINED HEREIN ARE BASED ON TESTS AND DATA WHICH WE BELIEVE TO BE RELIABLE, BUT THE ACCURACY OR COMPLETENESS THEREOF IS NOT GUARANTEED AND NO WARRANTY OF ANY KIND IS MADE WITH RESPECT THERETO. THIS INFORMATION IS NOT INTENDED AS A LICENSE TO OPERATE UNDER OR A RECOMMENDATION TO PRACTICE OR INFRINGE ANY PATENT OF THIS COMPANY OR OTHER COVERING ANY PROCESS, COMPOSITION OF MATTER OR USE. SINCE THE COMPANY SHALL HAVE NO CONTROL OF THE USE OF THE PRODUCT DESCRIBED HEREIN, THE COMPANY ASSUMES NO LIABILITY OF LOSS OR DAMAGE INCURRED FROM THE PROPER OR IMPROPER USE OF SUCH PRODUCT.



GlucaGen® Hypokit

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 1/23/2015

Version: 1.0

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

1.1. Product identifier

Product name : GlucaGen® Hypokit
Formula : $C_{153}H_{225}N_{43}O_{49}S$

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

Use of the substance/mixture : Drug Product. GlucaGen is used to treat severe hypoglycemic (low blood sugar) reactions which may occur in patients with diabetes mellitus treated with insulin. GlucaGen is indicated for use during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract.

1.3. Details of the supplier of the safety data sheet

Novo Nordisk
800 Scudders Mill Road
Plainsboro, NJ 08536
T 800-727-6500
www.novonordisk-us.com

1.4. Emergency telephone number

Emergency number : 800-727-6500

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Skin Sens. 1 H317

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US) :



GHS07

Signal word (GHS-US)

: Warning

Hazard statements (GHS-US)

: H317 - May cause an allergic skin reaction

Precautionary statements (GHS-US)

: P261 - Avoid breathing dust, mist
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear appropriate PPE
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P321 - Specific treatment (see see Section 4 on this label)
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
P362+P364 - Take off contaminated clothing and wash it before reuse
P501 - Dispose of contents/container to comply with local/national regulations

2.3. Other hazards

Other hazards not contributing to the classification

: Inactive ingredients include: lactose monohydrate and sterile water for reconstitution.

2.4. Unknown acute toxicity (GHS-US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

Full text of H-phrases: see section 16

3.2. Mixture

Name	Product identifier	%	GHS-US classification
GlucaGen HypoKit 1 mg powder and solvent for solution for injection Glucagon [rDNA origin] hydrochloride (active ingredient)	(CAS No) 16941-32-4	100	Skin Sens. 1, H317

Glucagen® Hypokit

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according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
First-aid measures after inhalation	: Remove person to fresh air. If signs/symptoms continue, get medical attention.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash contaminated clothing before reuse.
First-aid measures after 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.
First-aid measures after ingestion	: Rinse mouth. Drink plenty of water. Seek medical advice in case of persistent discomfort.

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

Symptoms/injuries after inhalation	: Not investigated. Inhalation of mist/dust containing protein may cause sensitization.
Symptoms/injuries after skin contact	: May cause irritation by the active substance or any of the excipients. Hypersensitivity reactions, including anaphylaxis have been reported with Glucagen® Hypokit.
Symptoms/injuries after eye contact	: May cause irritation. Avoid contact with the eyes.
Symptoms/injuries after ingestion	: Not expected to be active orally. Absorption is not expected. Ingestion is not known to cause health effects.
Symptoms/injuries upon intravenous administration	: Allergic reactions may occur and include generalized rash, and in some cases anaphylactic shock with breathing difficulties, and hypotension.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Fire hazard	: The product is not readily flammable.
Reactivity	: Not reactive under normal use and conditions.

5.3. Advice for firefighters

Protection during firefighting	: Positive pressure self-contained breathing apparatus (SCBA) and structural firefighters' protective clothing will provide adequate protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Seek fresh air.

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.

6.2. Environmental precautions

Under normal use, this product is not expected to impact the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment	: Do not touch or walk through spilled material.
Methods for cleaning up	: Absorb with non-combustible material and transfer to containers.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Do not get in eyes, on skin, or on clothing. Use personal protective equipment as required.
Hygiene measures	: Do not eat, drink or smoke when using this product. Practice good housekeeping. Wash thoroughly after handling. Change contaminated clothing. Do not reuse until laundered.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Before Reconstitution: The GlucaGen package may be stored up to 24 months at controlled room temperature 20° to 25° C (68° to 77° F) prior to reconstitution. Do not freeze. Keep in the original package to protect from light. GlucaGen should not be used after the expiry date on the vials. After Reconstitution: Reconstituted GlucaGen should be used immediately. Discard any unused portion. If the solution shows any sign of gel formation or particles, it should be discarded.
Incompatible products	: Heat sources.
Maximum storage period	: 24 months
Storage temperature	: 20 - 25 °C

7.3. Specific end use(s)

Drug Product. GlucaGen is used to treat severe hypoglycemic (low blood sugar) reactions which may occur in patients with diabetes mellitus treated with insulin. GlucaGen is indicated for use during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Contains no substances subject to reporting requirements.

8.2. Exposure controls

Appropriate engineering controls	: Work must be done with effective mechanical ventilation (e.g. local extractor fan). There must be access to running water and eye wash.
Personal protective equipment	: Avoid all unnecessary exposure.
Hand protection	: Polyvinylchloride (PVC) / Nitrile rubber gloves.
Eye protection	: Eye protection such as chemical splash goggles and/or face shield must be worn when possibility exists for eye contact due to splashing or spraying liquid. Contact lenses should not be worn.
Skin and body protection	: PVC gloves, nitrile rubber or similar protection are recommended for waste clear-up and manufacturing operations.
Respiratory protection	: Not normally required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid/solution
Appearance	: White powder/ aqueous solution.
Molecular mass	: 3483 g/mol
Color	: White. Clear when reconstituted.
Odor	: No special smell.
Odor threshold	: No data available
pH	: 2.5 - 3.5
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in water.
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available

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Oxidising properties	: No data available
Explosive limits	: No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

Not reactive under normal use and conditions.

10.2. Chemical stability

Product is stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No known incompatibilities.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified pH: 2.5 - 3.5
Serious eye damage/irritation	: Not classified pH: 2.5 - 3.5
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (The weight of evidence indicates that GlucaGen is not different from glucagon pancreatic origin and does not pose a genotoxic risk to humans.)
Carcinogenicity	: Not classified (Long term studies in animals to evaluate carcinogenic potential have not been performed. Several studies have been conducted to evaluate the mutagenic potential of glucagon. The mutagenic potential tested in the Ames and human lymphocyte assays, was borderline positive under certain conditions for both glucagon (pancreatic) and glucagon (rDNA) origin. In vivo, very high doses (100 and 200 mg/kg) of glucagon (both origins) gave a slightly higher incidence of micronucleus formation in male mice but there was no effect in females.)
Reproductive toxicity	: Not classified (GlucaGen (rDNA origin) was not tested in animal fertility studies. Studies in rats have shown that pancreatic glucagon does not cause impaired fertility.)
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: Not investigated. Inhalation of mist/dust containing protein may cause sensitization.
Symptoms/injuries after skin contact	: May cause irritation by the active substance or any of the excipients. Hypersensitivity reactions, including anaphylaxis have been reported with Glucagen® Hypokit.
Symptoms/injuries after eye contact	: May cause irritation. Avoid contact with the eyes.
Symptoms/injuries after ingestion	: Not expected to be active orally. Absorption is not expected. Ingestion is not known to cause health effects.
Symptoms/injuries upon intravenous administration	: Allergic reactions may occur and include generalized rash, and in some cases anaphylactic shock with breathing difficulties, and hypotension.

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SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations

: The product is not hazardous waste. Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with DOT

Not regulated for transport

Additional information

Other information

: No supplementary information available.

ADR

Transport document description

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

Glucagen HypoKit 1 mg powder and solvent for solution for injection Glucagon [rDNA origin] hydrochloride (active ingredient) (16941-32-4)

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

15.2.2. National regulations

No additional information available

Glucagen® Hypokit

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15.3. US State regulations

No additional information available

SECTION 16: Other information

Data sources

- : Novo Nordisk Medical Information for Health Care Professionals. [<http://www.novonordiskmedicalinformation.com/products.aspx>]. U.S. National Library of Medicine: DAILY MED [<http://dailymed.nlm.nih.gov/dailymed/index.cfm>].

Training advice

- : No special training is necessary but a thorough knowledge of this safety data sheet is assumed.

Full text of H-phrases: see section 16:

Skin Sens. 1	Sensitisation — Skin, category 1
H317	May cause an allergic skin reaction

NFPA health hazard

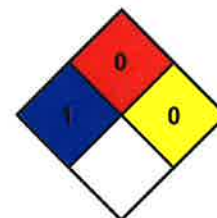
- : 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.

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.



SDS US (GHS HazCom 2012)

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



SAFETY DATA SHEET

1.0 IDENTIFICATION

Product: Grafco® Silver Nitrate Applicators

General Use: Cauterization of wounds and ulcers

Company Name:
GF Health Products, Inc.

Emergency Telephone Number:
800-472-4346 (Normal Business Hours)

Address:
2935 Northeast Parkway
Atlanta, GA 30360

Telephone Number for Information:
800-472-4346 (Normal Business Hours)

Date Issued: 08/13/2003

Date Revised: 09/19/2014

CHEMTREC CHEMICAL TRANSPORTATION 24 HOUR EMERGENCY TELEPHONE
DOMESTIC/ NORTH AMERICA 800-424-9300
INTERNATIONAL 703-527-3887 (CALL COLLECT)

2.0 HAZARD(S) IDENTIFICATION

EMERGENCY OVERVIEW: Silver nitrate/potassium nitrate solid impregnated on tip of wooden applicator is a strong irritant to skin and tissue. Toxic if ingested.

Primary Route(s) of Entry (for product): Inhalation: No Skin: Yes Ingestion: No Other: No

POTENTIAL HEALTH EFFECTS:

Note: Since the product has not been tested as a whole, the health effects of the individual ingredients are given in order to provide adequate warning to persons using the silver nitrate applicators.

Acute Effects of Overexposure:

Eye Contact: Contact with silver nitrate/potassium nitrate solid impregnated on tip of wooden applicator may cause irritation, the degree of which depends on the concentration and period of contact. Symptoms may include burning, tearing, and redness.

Skin Contact: Contact with silver nitrate/potassium nitrate solid impregnated on tip of wooden applicator may cause irritation, the degree of which depends on the concentration and period of contact. Symptoms may include redness and burning.

Inhalation: Inhalation of airborne silver nitrate particles may cause irritation of the respiratory tract.

Ingestion: Poisonous. If swallowed, can cause severe gastroenteritis and can be fatal. Due to its causticity, large doses of ingested silver nitrate may cause a burning sensation in the throat, violent abdominal pain, vomiting, collapse, and death.

Chronic Effects of Overexposure:

It is reported in the literature that chronic introduction of significant amounts of silver compounds into the blood stream and subsequent deposition of the reduced silver in various tissues of the body may result in the production of a generalized permanent grayish pigmentation of the skin and mucous membranes, a condition known as argyria, with no constitutional symptoms and no physical disability. The introduction of fine particles of silver through breaks in the skin produces a local pigmentation at the site of the injury. Localized argyria of the skin is rare. It has been concluded that on the average, 3.8 grams of orally administered silver nitrate causes argyria. The inhalation of silver powder over long periods has been concluded to cause pulmonary changes.

Chronic exposure to potassium nitrate can cause anemia, nephritis and methemoglobinemia.

Carcinogenicity: NTP: No IARC Monographs: NO OSHA: No

Medical Conditions Generally Aggravated by Exposure (to silver nitrate): Pre-existing diseases of the lungs, skin, eye, and other mucous membranes.

3.0 COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	% Weight	OSHA Airborne Particulate Permissible Exposure Limit (PEL, TWA^A)	ACGIH Airborne Particulate Threshold Limit Value (TLV₁TWA₁)
Silver Nitrate ^B	7761-88-8	75	0.01 mg/m ³	0.01 mg/m ³ , as AG metal
Potassium Nitrate	7757-79-1	25	Not established ^C	Not established ^C

NOTE: The chemicals above are impregnated into the tip of a wooden applicator. The weight percentages indicated above represent the relative proportions of the active ingredients and do not take into account the weight of the applicator¹.

^ATWA – Values given are 8 hour time-weighted averages, unless otherwise specified.

^BDenoted ingredient is a SARA Title III, Section 131 listed toxic chemical (silver compounds).

^CNot established – Substance not assigned a specific PEL or TLV. Substance regulated by OSHA as particulates not otherwise regulated (PNOR, PELs – 15 mg/m³ total dust. 5 mg/m³ respirable fraction) and by ACGIH as particulates not otherwise classified (PNOC, TLV – 10 mg/m³ total dust containing no asbestos and less than 1% crystalline silica) and is considered nuisance dust.

4.0 FIRST-AID MEASURES

Inhalation: Remove to fresh air and seek medical attention.

Eye Contact: With eyes held wide open, wash thoroughly with water for 15 minutes. Do not wear contact lenses.

Skin Contact: Immediately remove contaminated clothing and wash thoroughly with soap and water.

Ingestion: Drink copious amounts of water or milk. Avoid vomiting which may cause risk of perforation. Seek medical attention.

5.0 FIRE-FIGHTING MEASURES

Flash Point (Method Used): For product, not applicable.

Flammable Limits: Not applicable for product LEL: Not applicable UEL: Not applicable

Autoignition Temperature: Not applicable for product.

General Hazard: The impregnated solid is an oxidizer. May release toxic or irritating vapors under fire conditions.

Fire Fighting Instructions: As appropriate for surrounding fire. It is not believed that the product would be a significant hindrance to extinguishing methods used for the surrounding fire, due to the small amount of impregnated chemical solid and product form.

Fire Fighting Equipment: Fire fighters and others who may be exposed to combustion products during fire should wear full protective clothing, including positive pressure self-contained breathing apparatus (SCBA). Wear SCBA with a full face-piece, operated in the positive pressure mode when fighting fires.

Hazardous Combustion Product: Acrid/irritating smoke, oxides of nitrogen, potassium oxide, and oxides of carbon.

NFPA Rating: Health: 1 Flammability: 1 Reactivity: 0 Special: OX (oxidizer)

6.0 ACCIDENTAL RELEASE MEASURES

Steps to be Taken in Case Material is Released or Spilled: Not applicable for product in final form (solid silver nitrate/potassium nitrate impregnated on tip of wooden applicator). Dispose of spent applicators in accordance with applicable federal, state, and local regulations.

7.0 HANDLING AND STORAGE

Storage Temperature and Pressure: Ambient temperature and pressure are adequate. This section lists precautions for safe handling and storage, including incompatibilities.

General: Store product in a dark, dry location, away from organic or other readily oxidizable materials. Keep container closed when not in use. Do not use in eyes. Keep away from children.

8.0 EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Local and/or general ventilation, as needed, to reduce employee exposures to below applicable OSHA PELs and ACGIH TLVs (see SECTION 3.0 COMPOSITION INFORMATION ON INGREDIENTS FOR PELs and TLVs), or other industry standards or guidelines on exposure. If respiratory protection is required, all appropriate requirements as set forth in 29 CFR 1910.134 must be met. A competent health professional should be consulted for respirator selection. Due to final product form and use, it is not believed that PELs or TLVs will be exceeded.

Protective Gloves: Latex, vinyl or rubber examination gloves in order to prevent unnecessary or accidental skin contact.

Eye Protection: Safety glasses to prevent accidental contact.

Other Protective Clothing or Equipment: No special clothing necessary.

9.0 PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point:	Decomposes @444° C, for silver nitrate	Freezing Point:	Not applicable
Vapor Pressure (mm Hg):	Not applicable	Specific Gravity (H2O=1):	>1, for silver nitrate
Vapor Density (AIR =1):	Not applicable	Evaporation Rate:	Not applicable
Melting Point:	414°F (212°C) for silver nitrate 663° (334°C) for potassium nitrate	Solubility in water:	Soluble, for silver nitrate
Appearance and Odor:	Grayish solid impregnated on tip of wooden applicator, practically odorless.		

10.0 STABILITY AND REACTIVITY

Stability: Product is stable at ambient temperature and pressure. Exposure of product to light may cause oxidation and discoloration of the impregnated applicator.

Conditions to avoid: Contact of product with easily oxidizable materials and other incompatible materials. Heat or high temperature may cause solid in tip of product to decompose, possibly releasing small amount of toxic or irritating vapors.

Incompatible Materials: Easily oxidizable materials.

Silver Nitrate is incompatible with alkalies, antimony salts arsenites, bromides, carbonates, chlorides, iodides, vegetable decoctions and extracts; acetylene, acetylene + ammonium hydroxide, acetylides, ammonium hydroxide, arsenic, chloride phosphine, phosphonium iodide, phosphorous isocyanate, and plastics.

Potassium Nitrate is incompatible with antimony, antimony trisulfide, arsenic, arsenic disulfide, barium sulfide, boron, boron phosphide, calcium sulfide, copper phosphide, fluorine, germanium, germanium sulfide, sodium acetate, sodium hypophospite, sodium peroxide + dextrose, sulfur + arsenic trisulfide, titanium, titanium disulfide, trichloroethylene, zinc, zirconium.

Hazardous Decomposition: When heated to decomposition, will emit small amounts of toxic NOx fumes and potassium oxide.

Hazardous Polymerization: Will Not Occur.

11.0 TOXICOLOGICAL INFORMATION

For silver nitrate

LD50 oral mouse – 50 mg/kg

LDLo unknown route, man – 29 mg/kg

Eye rabbit – 1 mg, severe irritation

For potassium nitrate:

LD50 oral rabbit – 1901 mg/kg

Other toxicity data exist in literature.

12.0 ECOLOGICAL INFORMATION

No data available.

13.0 DISPOSAL CONSIDERATIONS

Waste Disposal Method: Dispose of in accordance with applicable federal, state, and local regulations. Consult an expert on the disposal of spent or recovered material. A qualified professional should perform a solid waste determination.

14.0 TRANSPORT INFORMATION

DOT Hazard Classification: OXIDIZER

Potassium Nitrate: UN 1486

Silver Nitrate: UN 1493

Regulatory Reference: 49CFR 172.101

IATA: Nitrates, inorganic, n.o.s. UN# 1477

15.0 REGULATORY INFORMATION

EPA SARA Title III Hazard Categorization: Based on the components of the tip of the silver nitrate applicators, the product is categorized as an immediate (acute) health hazard and delayed (chronic) health hazard.

FEPA SARA Title III Section 302 Extremely Hazardous Substances (EHSs): No ingredients in this product are listed as an EHS under Section 302 of SARA Title III.

16.0 OTHER INFORMATION

All information, recommendations, and suggestions appearing herein concerning the product are based upon data believed to be reliable. It is the user's responsibility to determine that safety, toxicity, and suitability for their own use of the product described herein, and to comply with all applicable regulations. Since the actual use by others is beyond the MSDS developer's control, no guarantee, expressed or implied is made by Henry Schein, Inc., as to the effects of such use, the results to be obtained or the safety and toxicity of the product nor does Henry Schein, Inc. assume any liability arising out of use by others of the product referred to herein. This MSDS is not intended as a license to operate under, or recommendation to infringe on, any patents. Appropriate warnings and safe handling procedures should be provided to handlers and users.

Note: CHEMTREC and NATIONAL RESPONSE CENTER emergency telephone numbers are to be used only in the event of CHEMICAL EMERGENCIES involving a spill, leak, fire, exposure, or accident involving chemicals. All non-emergency questions should be directed to Henry Schein, Inc., for assistance.

PREPARED BY: GF Health Products, Inc.
Revision No.: E Date: 09/19/14



February 22, 2016

RE: SDS Exemption for Hibiclens

To Whom It May Concern,

Per Occupational Safety and Health (OSHA) regulation 29 CFR 1910.1200(b)(5)(iii), the following are exempt from the hazard communication system requirements (including hazard labels and safety data sheets):

Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151 et seq.), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture

Hibiclens is considered an OTC drug regulated under a New Drug Application (NDA) by the US Food and Drug Administration (FDA) and, as such, is exempt from SDS requirements.

If you have any questions or need additional information, I can be contacted by email at Jennifer.register@molnlycke.com or by phone at (470) 375-0050, ex: 9050.

Sincerely,

Jennifer Register
Sr. Regulatory Affairs Specialist
Americas

MSDS# L-AR-00028

Effective: 10/23/2009

Product: **Hydralazine Hydrochloride Injection, USP**

Revision: 1



Luitpold Pharmaceuticals

AMERICAN REGENT, INC.

MATERIAL SAFETY DATA SHEET**Section 1: PRODUCT AND COMPANY INFORMATION**

Luitpold Pharmaceuticals, Inc.
P.O. Box 9001
Shirley, New York 11967
(800) 645-1706
(631) 924-4000

Chemtrec 24/7 Emergency Telephone Number
Domestic North America: (800) 424-9300
International: +1 703-527-3887

PRODUCT NAME: **Hydralazine Hydrochloride Injection, USP**

PRODUCT CODE (NDC): **20 mg/mL: 0517-0901-25**

Section 2: HAZARDS IDENTIFICATION**EMERGENCY OVERVIEW**

Appearance / Odor	Clear, colorless to slightly yellow solution with a characteristic odor of parabens.
WARNING!	
Skin, eye, respiratory and gastrointestinal irritant	Causes irritation of the eyes, skin, gastrointestinal and respiratory tracts.
Toxicity to fish/aquatic organisms	Product is not known to be toxic to fish.
<i>Potential Health Effects: See Section 11 for more information</i>	
Likely Routes of Exposure	Eye contact, skin contact, inhalation and ingestion.
Eye	Causes irritation of the eye.
Skin	Causes irritation of the skin.
Inhalation	Causes irritation of the upper and lower respiratory tract.
Ingestion	Causes irritation of the gastrointestinal tract.
Skin Absorption	Product can not be absorbed through the skin.
Medical Conditions Aggravated by Exposure	Personnel with impaired cardiovascular and hemopoietic systems should minimize their exposure to this product. Pregnant workers should avoid exposure to this product.
Target Organs	Eyes, skin, lungs, liver, kidneys, central nervous system, cardiovascular and hemopoietic systems.

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Product: **Hydralazine Hydrochloride Injection, USP**

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Section 2: HAZARDS IDENTIFICATION (continued)

Potential Environmental Effects:
See Section 12 for more information

This product is not known to be toxic to fish.

This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.

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

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS

Component	CAS Number	Percentage (%) by Weight
Hydralazine Hydrochloride	304-20-1	2.0 percent
Methylparaben	99-76-3	0.1 percent
Propylparaben	94-13-3	0.04 percent
Propylene Glycol	57-55-6	10.4 percent
Sodium Hydroxide	1310-73-2	used for pH adjustment
Hydrochloric Acid	7647-01-0	used for pH adjustment
Water for Injection	7732-18-5	87.5 percent

Section 4: FIRST AID MEASURES

Eye Contact	Causes irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.
Skin Contact	Causes irritation to the skin. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.
Inhalation	Causes irritation of respiratory tract. Remove person to fresh air. Remove contaminated clothing. Seek medical attention.
Ingestion	Ingestion of product may cause irritation, nausea and diarrhea. Flush mouth out with water. Seek medical attention.
Injection	See prescribing information.
Note to Physicians	Exposure to this product may result in headache, nausea, vomiting diarrhea, palpitations, tachycardia, hypotension and flushing of the skin. See prescribing information.

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Product: **Hydralazine Hydrochloride Injection, USP**

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Section 5: FIRE FIGHTING MEASURES

Suitable Extinguishing Media	Water spray, foam, dry chemical or Carbon Dioxide (CO ₂). Caution: CO ₂ will displace air in confined spaces and may cause an Oxygen deficient atmosphere.
Unsuitable Extinguishing Media	None.
Hazardous Combustion Products	When heated, Hydralazine solution thermally decomposes to form toxic vapors. (i.e. Carbon Monoxide, Carbon Dioxide, Halogenated Compounds and Nitrogen Oxides).
<u>Protection for Firefighters:</u> Hydralazine solution thermally decomposes to form toxic vapors. Vapors may be irritating to eyes and skin and toxic to respiratory tract. Firefighters are to wear self-contained breathing apparatus (SCBA) and full turn out gear (Bunker gear). Cool containers with water spray and use caution when approaching.	

Section 6: ACCIDENTAL RELEASE MEASURES

Personnel Precautions	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Environmental Precautions	This material is not considered a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Minimize the use of water to prevent environmental contamination.
Methods of Containment	Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.
Methods of Clean Up	Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.
Other Information	A spill of this material does not need to be reported to the National Response Center.

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Product: **Hydralazine Hydrochloride Injection, USP**

Revision: 1

Section 7: HANDLING AND STORAGEHandling:

As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of mists or vapors associated with the product. Avoid contact with skin, eyes or clothing. Do not mix with other drugs.

Use in a well ventilated area. Wash thoroughly after handling.

Storage:

Store in a well ventilated area. Keep containers closed when not in use. Product residue may remain in empty containers. Observe all label precautions until container is cleaned, discarded or destroyed.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines	OSHA PEL	ACGIH TLV	OTHER
Hydralazine Hydrochloride	Not listed	Not listed	
Methylparaben	Not listed	Not listed	
Propylparaben	Not listed	Not listed	
Propylene Glycol	Not listed	Not listed	
Hydrochloric Acid	5 parts per million - Ceiling	2 parts per million - Ceiling	
Sodium Hydroxide	2 milligrams / cubic meter - 8 hour TWA	2 milligrams / cubic meter - Ceiling	
Water for Injection	Not Listed	Not Listed	
Personal Protective Equipment	Description		
Ventilation	Local exhaust or general ventilation is recommended.		
Respiratory Protection	Under normal conditions of product use, respiratory protection is not required. When required, use a NIOSH approved air purifying respirator with combination P-100 / organic vapor / acid gas cartridges.		
Eye Protection	Wear ANSI approved chemical splash goggles or safety glasses.		
Skin Protection	When administering this product to patients, wear nitrile or latex gloves. Use Tyvek™ SL or equivalent coveralls, PVC booties and nitrile gloves for clean up activities.		

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Color	Clear, colorless to slightly yellow solution
Odor / Odor Threshold	Characteristic odor (i.e. parabens)
Physical State	Liquid
pH	3.4 to 4.4
Freezing Point	Below 32 degrees Fahrenheit
Boiling Point	Approximately 230 degrees Fahrenheit
Flash Point	Not applicable
Evaporation Rate	Not applicable
Flammability	Nonflammable, noncombustible

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Product: **Hydralazine Hydrochloride Injection, USP**

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Section 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Upper Flammable Limit	Not applicable
Lower Flammable Limit	Not applicable
Vapor Pressure	Not applicable
Vapor Density	Not applicable
Specific Gravity	Approximately 1.0
Solubility (water)	Soluble in water
Partition Coefficient	Not applicable
Auto-ignition Temperature	Not applicable
Percent Volatile	0 percent
Volatile Organic Compounds (%)	0 percent

Section 10: STABILITY AND REACTIVITY

Stability	Stable.
Conditions to Avoid	Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors.
Incompatible Materials	Reactive with oxidizers.
Hazardous Decomposition Products	Carbon Monoxide, Carbon Dioxide, Halogenated Compounds and Nitrogen Oxides may be released by thermal decomposition.
Possibility of Hazardous Reactions	Hazardous polymerization will not occur.

Section 11: TOXICOLOGY INFORMATION

Acute Effects	
Oral (LD ₅₀)	LD ₅₀ : 280 mg/kg oral - rat LD ₅₀ : 188 mg/kg oral - mouse
Intravenous (LD ₅₀)	LD ₅₀ : 71 mg/kg intravenous - mouse LD ₅₀ : 34 mg/kg intravenous - rat
Intraperitoneal (LD ₅₀)	LD ₅₀ : 83 mg/kg intraperitoneal - mouse
Dermal (LD ₅₀)	No data available.
Inhalation	Causes respiratory irritation.
Eye Irritation	Causes eye irritation.
Skin Irritation	Causes skin irritation.
Sensitization	Product is considered a skin sensitizer.

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Section 11: TOXICOLOGY INFORMATION (continued)	
Chronic Effects	
Organ Systems	Prolonged or repeated exposure may lead to damage to the liver, lungs, kidneys, cardiovascular, hemopoietic and central nervous system. Chronic exposure may lead to an autoimmune response.
Carcinogenicity	Two animal studies illustrated that Hydralazine is considered carcinogenic. No adequate and well controlled studies in humans have been conducted.
Mutagenicity	Hydralazine was found to be mutagenic in bacteria. No adequate and well controlled studies in humans regarding the mutagenic effects of Hydralazine have been conducted.
Reproductive Effects	No adequate and well controlled studies in humans or animals regarding the reproductive effects of Hydralazine have been conducted.
Developmental Effects	Based on animal test data, Hydralazine is considered a teratogen. No adequate and well controlled studies in humans have been conducted. Classified as Pregnancy Category C.

Section 12: ECOLOGICAL INFORMATION	
Ecotoxicity	No data available.
Persistence / Degradability	Short term products of biodegradation are not likely. Long term degradation products may arise.
Bioaccumulation / Accumulation	No applicable bioaccumulation is expected in the environment.
Mobility in Environment	Appreciable volatilization is not expected into the air.

Section 13: DISPOSAL CONDITIONS	
Disposal	Do not mix with other substances. Dispose of in accordance with Federal, state and local regulations. Contact your state or local government environmental and / or sanitation department for guidance on disposal.

Section 14: TRANSPORTATION INFORMATION	
Regulatory Agency	Shipping Description
US DOT (ground)	Not considered a DOT regulated material - Non hazardous for shipment.
Canadian TDG (ground)	See US DOT.
IATA (air)	Not considered a DOT regulated material - Non hazardous for shipment.

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Product: **Hydralazine Hydrochloride Injection, USP**

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Section 15: REGULATORY INFORMATION

STATE RIGHT TO KNOW	Refer to the applicable state to determine applicability.
California Safe Drinking Water & Toxic Enforcement Act (Prop 65)	This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins under California Proposition 65.
RTECS Number	TH9000000
TSCA	8b Inventory - Hydralazine
NFPA Rating	Health - 3, Fire - 1, Reactivity - 0
WHMIS (Canada)	D-1B: Causes immediate and serious toxic effects D-2A: Causes other toxic effects

Section 16: OTHER INFORMATION

Hydralazine Hydrochloride Injection, USP is indicated for severe essential hypertension when the drug cannot be given orally or when there is an urgent need to lower blood pressure.

Refer to Luitpold / American Regent's prescribing information for further information at http://www.americanregent.com/product_index.asp.

Prepared By: Christopher Seniuk CIH CSP

The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.

Ipratropium Bromide, 0.5 mg/ Albuterol Sulfate, 3.0 mg Inhalation Solution, USP

Effective Date: 02-01-2017



Revision date: 02-01-2017

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Nephron Pharmaceuticals Corporation
 4500 12th Street Extension
 West Columbia, SC 29172-3025

(803) 569-2800
 (800) 443-4313 (24 hour contact)

PRODUCT NAME: Ipratropium Bromide, 0.5 mg/ Albuterol Sulfate, 3.0 mg Inhalation Solution, USP
 COMMON NAME: Ipratropium Bromide/ Albuterol Sulfate
 CHEMICAL NAME: Ipratropium Bromide:
 8-azoniabicyclo [3, 2, 1]-octane, 3-(3-hydroxy-1-oxo-2-phenylpropoxy)-8-methyl-8-(1-methylethyl)-, bromide (endo, syn)-, (±)-, monohydrate
 Albuterol Sulfate:
 '- [tert-butylamino-methyl] -4-hydroxy-m-xilene--'-diol sulfate (2:1) (salt)

INTENDED USE: Pharmaceutical product used as bronchodilator

SECTION 2: HAZARD(S) IDENTIFICATION

ROUTE OF ENTRY: Inhalation, ingestion, eyes/skin contact.

TARGET ORGANS: Liver, GI tract, adrenals, male reproductive organs and eyes.

POTENTIAL HEALTH HAZARDS

Contraindications: Although rare, this product can cause immediate hypersensitivity in patient. Therefore, this product should not be used by patients who have had a previous allergic reaction to ipratropium bromide, albuterol sulfate or its derivatives.

Carcinogenicity: (NTP) No (IARC) No (OSHA) No

Chronic Effects: Possible hypersensitization (development of abnormal sensitivity).

SECTION 3: COMPOSITON / INFORMATION ON INGREDIENTS

NAME: Ipratropium Bromide, 0.5 mg/ Albuterol Sulfate, 3.0 mg Inhalation Solution, USP
 CAS#: 66985-17-9/ 51022-70-9
 Other Limits: Not Established
 NAME: Water for Injection
 CAS#: 7732-18-5

SECTION 4: FIRST AID MEASURES

If In Eyes: Remove contact lenses if necessary. Flush with large amounts of cool water for at least 15 minutes. Obtain medical attention if blurred vision or sensitivity to light occurs.

If On Skin: Wash affected areas with soap and water after removing contaminated clothing. Obtain medical attention if contamination is significant and/or a skin reaction is evident.

Ipratropium Bromide, 0.5 mg/ Albuterol Sulfate, 3.0 mg Inhalation Solution, USP

Effective Date: 02-01-2017

- If Inhaled: May cause irritation and hypersensitivity (anaphylactic) in some individuals. Inhalation of a liquid preparation is not likely. Evaporation is minimal at controlled room temperatures.
- If not breathing, give artificial respiration or CPR. If breathing is difficult, give oxygen. Obtain medical attention and remove to fresh air.
- If Ingested: Move affected person to a well-ventilated area and get immediate medical attention. If breathing becomes difficult, give oxygen. If breathing stops, give artificial respiration and seek medical attention.

SECTION 5: FIRE FIGHTING MEASURES

- FLASH POINT/TEST METHOD: Unknown.
- LEL/UEL: Unknown.
- SPECIAL PROPERTIES RELATED TO FIRE HAZARD: None.
- STORAGE OR HANDLING CONDITIONS TO BE AVOIDED: Extreme Heat.
- EXTINGUISHING MEDIA: Water Spray, Multipurpose Dry Chemical.
- FIRE-FIGHTING PROCEDURES: Wear full protective clothing and use self-contained breathing apparatus (SCBA).

SECTION 6: ACCIDENTAL RELEASE MEASURES

SPILL RESPONSE PROCEDURES (Liquid, Solid, Gas/Vapor):

Protective equipment may be necessary for spills, (See Section 8, "Exposure Controls / Personal Protection" for guidance).

For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, collect spillage by carefully sweeping or wiping and place in a labeled, sealed container for disposal.

ACCIDENTAL RELEASE: Clean up spills immediately, observing precautions in Section 8 - "Exposure Controls / Personal Protection". Remove or decontaminate all residues in accordance with federal, state and local regulations.

SECTION 7: HANDLING AND STORAGE

- HANDLING: Avoid contact with eyes, skin, and clothing.
- STORAGE: Store between 36° and 77° F. Discard if solution becomes discolored.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS: No special ventilation required.

PERSONAL PROTECTION:

- Respiratory: Not required under normal conditions of therapeutic use. See Section 5 " Fire-Fighting Measures" for respiratory protection in the event of a fire.
- Eye: Not required for recommended dosage and administration. Workers should wear adequate eye protection if splash hazard exists.
- Clothing: Adequate protective clothing should be worn to prevent occupational skin contact.
- Gloves: When routine handling or spill cleanup may result in skin contact, impermeable (e.g., latex) gloves should be worn.
- Work Practices: Special care should be taken to ensure that contaminated clothing, equipment and work surfaces are properly cleaned after use. Wash hands and other areas of skin contact thoroughly after handling this material. Contaminated clothing should be cleaned or disposed of.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AND ODOR:	Clear, aqueous solution with a little or no odor.
PHYSICAL STATE:	Liquid.
MELTING POINT:	Not determined.
BOILING POINT:	Not determined.
SOLUBILITY/MISCIBILITY (%w/v):	Not determined.

SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY:	Stable.
CONDITIONS TO AVOID:	Not determined.
INCOMPATIBILITY WITH OTHER MATERIALS:	Not determined. No known incompatibilities have been identified for this product.
HAZARDOUS DECOMPOSITION PRODUCTS:	Hazardous decomposition products have not been determined.

SECTION 11: TOXICOLOGICAL INFORMATION**THE RISK OF HEALTH HAZARDS MAY BE REDUCED WHEN HANDLED IN UNIT DOSAGE FORM.**

PHARMACOLOGICAL ACTIVITY:	The active component is albuterol sulfate. Albuterol sulfate is a β_2 -adrenergic bronchodilator used for the therapeutic effect of bronchial smooth muscle relaxation. This product is used for the prevention and relief of bronchospasm in patients with reversible obstructive airway disease (asthma) and for acute attacks of bronchospasm.
OCCUPATIONAL EXPOSURE LIMITS:	For products, the estimated safe working level is an eight-hour time-weighted average (TWA) of 10 mcg/m ³ .
ACUTE TOXICITY:	Overexposure to the drug in the occupational setting may result in the same adverse effects which have been observed when albuterol sulfate is used medically. (See "Repeat Dose Toxicity" and "Clinical Safety", below). Albuterol sulfate may be absorbed following ingestion, inhalation, and to a limited extent, through the skin.
REPEAT DOSE TOXICITY:	When used medically the following adverse effects have been reported: fine muscle tremors (especially the hands), muscle cramps, nausea or vomiting, headache, vertigo (dizziness), nervousness, heartburn, and rapid pulse, palpitations, and increased blood pressure. Hypersensitivity reactions (ranging from mild to life-threatening), such as urticaria (hives), skin rash, bronchospasm (constriction of the air passages in the lungs), and angioedema (swelling involving the skin and mucous membranes) have rarely occurred. In addition, albuterol sulfate may cause significant changes in blood pressure, extremely rapid heartbeat, seizures, low potassium levels, and may exacerbate the symptoms of pre-existent cardiovascular (heart and blood vessel) conditions and diabetes.
IRRITATION:	Products can cause eye irritation; avoid contact with the eyes. Products are irritating to the nose and throat.
SENSITIZATION:	Rarely, exposure to albuterol sulfate can cause an allergic rash with redness and itching of the skin. Exposure by inhalation can cause an allergic rash, difficulty breathing and swelling of the face and airways.
REPRODUCTIVE EFFECTS:	Albuterol sulfate causes birth defects in mice. Rare reports of cleft palate and limb defects have been received in offspring of patients being treated with albuterol sulfate. There are no adequate and well-controlled studies of the effects of albuterol sulfate in pregnant women. Albuterol sulfate should be used

Ipratropium Bromide, 0.5 mg/ Albuterol Sulfate, 3.0 mg Inhalation Solution, USP

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during pregnancy only if the potential benefit justifies the potential risk to the fetus. For recommended dosage and administration, Albuterol Sulfate Inhalation Solution 3.0mg is classified as "Pregnancy Category C". It is not known whether this drug is excreted in human milk. A decision should be made whether to discontinue nursing or to discontinue using the drug, taking into account the importance of the drug to the mother. Precautions should be taken to limit the exposure to Albuterol Sulfate Inhalation Solution, 3.0mg while pregnant or nursing: medical evaluation of exposure and attention to compliance with standard operating procedures and/or other workplace health and safety directives is advised.

GENOTOXICITY:

There is no evidence that albuterol sulfate is mutagenic (causing changes in genetic material) or impairs fertility in standard tests.

CARCINOGENICITY:

Albuterol sulfate was not carcinogenic in standard tests with mice and hamsters. Albuterol sulfate causes benign tumors to rats treated daily for 2 years with doses which are much greater than the recommended maximum dose for human medical use. The relevance of this finding to humans is not known.

CLINICAL SAFETY:

Individuals known to be hypersensitive to β -adrenergic agents like albuterol sulfate should not be exposed. Persons with cardiovascular disorders (including coronary artery disease, heart rhythm abnormalities and high blood pressure), seizure disorders (epilepsy) hyperthyroidism, or diabetes may experience worsening of symptoms from occupational exposure. Also, persons using Albuterol Sulfate Inhalation Solution, 3.0mg or other medications in the same therapeutic class (β_2 -adrenergic receptor agonists), or taking monoamine oxidase inhibitors or tricyclic antidepressants, may have increased sensitivity to the effects of albuterol sulfate in the occupational setting.

SECTION 12: ECOLOGICAL INFORMATION**ENVIRONMENTAL FATE:**

Albuterol compartmentalizes into the aquatic environment.

ENVIRONMENTAL EFFECTS:

Albuterol is not readily biodegradable in water or soil and is unlikely to bioaccumulate. It has toxicity to receptors in the aqueous environment at levels greater than 83.2 mg/L.

ROUTINE

Unused product should be disposed of at an approved facility in accordance with federal, state and local regulations.

SECTION 14: TRANSPORT INFORMATION**Component 1 or Formulation 1:**

Albuterol Sulfate Inhalation Solution, 3.0mg

US Department of Transportation**Proper Shipping Name:**

Pharmaceutical for Interstate Commerce

IATA/ICAO**Proper Shipping Name:**

Not Regulated

IMDG**Proper Shipping Name:**

Not Regulated

RQ: None

Marine Pollutant: No

SECTION 15: REGULATORY INFORMATION**EC PACKAGING AND LABELING FOR SUPPLY:**

Not applicable.

OTHER LEGISLATION:

Not regulated.

Ipratropium Bromide, 0.5 mg/ Albuterol Sulfate, 3.0 mg Inhalation Solution, USP

Effective Date: 02-01-2017

SECTION 16: OTHER INFORMATION

REVISION DATE: 02-09-2015

REVISION DATE: 07-22-2004

REVISION DATE: 06-26-2014

SUPERSEDES: 01-23-2003

SUPERSEDES: 07-22-2004

TO THE BEST OF OUR KNOWLEDGE THE INFORMATION CONTAINED HEREIN IS ACCURATE AS OF THE DATE HEREOF. ANY DETERMINATION AS TO THE SUITABILITY OF THE PRODUCT FOR ANY PARTICULAR PURPOSE, ITS SAFE USE OR DISPOSAL, SHALL BE THE RESPONSIBILITY OF THE USER. THE INFORMATION CONTAINED HEREIN IS IN NO WAY INTENDED TO SUPPLEMENT, MODIFY, OR SUPERSEDE THE INFORMATION PROVIDED IN THE PRODUCT PACKAGE INSERT WITH RESPECT TO THE USE OF THE PRODUCT FOR MEDICAL PURPOSES. PLEASE REFER TO THE PRODUCT PACKAGE INSERT FOR INFORMATION REGARDING THE USE OF THE PRODUCT FOR MEDICAL PURPOSES.

Safety Data Sheet



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	<u>USA</u> Bristol-Myers Squibb Company P.O. Box 191 New Brunswick, New Jersey 08903 United States of America 1-800-332-2056	<u>Ireland</u> 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.	<u>Ireland</u> : 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.

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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-phrases	H-code(s)
<i>Hazardous components</i> 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

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					H335
<i>Other ingredients</i>					
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-phrases 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, fluoroquinolone 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.

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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/m ³ 8 hour-TWA (Skin)	--	--	--
Benzyl Alcohol		--	--	--
Sodium Hydroxide		2 mg/m ³ Ceiling	--	--
Hydrochloric Acid		2 ppm Ceiling	5 ppm MAK 7.6 mg/m ³ MAK 2 ppm TWA 3 mg/m ³ TWA 4 ppm Peak 6 mg/m ³ Peak 2 ppm MAK 3.0 mg/m ³ MAK	5 ppm STEL 1 ppm TWA 2 mg/m ³ TWA

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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.

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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

<i>Appearance</i>	
Physical State	liquid
Color	white to off-white
Form	suspension
<i>Odour</i>	
Odour	Not remarkable.
Odor Threshold	Not available
<i>pH</i>	
5 - 7	
<i>Other information</i>	
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	<u>Triamcinolone Acetonide</u> Mildly and/or transiently irritating to eyes <u>Benzyl Alcohol</u> Irritating to eyes.
Skin Irritation	<u>Triamcinolone Acetonide</u>

11. TOXICOLOGICAL INFORMATION

	Repeated exposure may cause skin dryness or cracking. skin thinning <u>Benzyl Alcohol</u> Mildly irritating to skin
Respiratory Irritation	<u>Triamcinolone Acetonide</u> May cause irritation of respiratory tract. <u>Benzyl Alcohol</u> Irritating to respiratory tract.
Sensitization	<u>Triamcinolone Acetonide</u> Not a dermal sensitizer Allergic contact dermatitis is quite rare but has been reported. <u>Benzyl Alcohol</u> 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 <u>Triamcinolone Acetonide</u> LD50 (mouse): 5,000 mg/kg <u>Benzyl Alcohol</u> 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 <u>Benzyl Alcohol</u> LD50 (rabbit): 2,000 mg/kg Acute inhalation toxicity <u>Benzyl Alcohol</u> LC50 (rat): 8.8 mg/l/4 H Acute toxicity (other routes of administration) <u>Triamcinolone Acetonide</u> LD50 (rat, subcutaneous): 13.1 mg/kg LD50 (mouse, subcutaneous): 132 mg/kg LD50 (mouse, intraperitoneal): 105 mg/kg
Repeated Dose Toxicity	<u>Benzyl Alcohol</u> 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	<u>Triamcinolone Acetonide</u> 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. <u>Benzyl Alcohol</u> Mutagenicity Assessment The weight of evidence demonstrates that this material is not genotoxic.

Carcinogenicity	<u>Triamcinolone Acetonide</u> 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. <u>Benzyl Alcohol</u> 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	<u>Triamcinolone Acetonide</u> 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	<u>Triamcinolone Acetonide</u> 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).

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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

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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.

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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-phrases R60: May impair fertility.
R61: May cause harm to the unborn child.
R64: May cause harm to breastfed babies.

S-phrases 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-phrases(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:

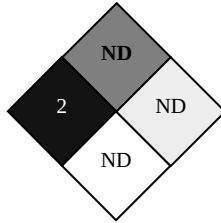
Not available

SDS preparation information

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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	

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*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)-838012435		Vietnamese
CHEMTREC Australia (Sydney)	+(61)-290372594		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 (Budapest)	+(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)-852603403		Swedish
CHEMTREC Switzerland (Zurich)	+(41)-435016715		German
CHEMTREC UK (London)	+(44)-870-8200418		English
CHEMTREC Bahrain (Bahrain)	+(973)-16159372		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

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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

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

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

Label Elements

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

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

SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP
(Hospira Inc.)
Revision date: 03-Aug-2016

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**Other Hazards**

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

Note:

This document has been prepared in accordance with standards for workplace safety, which 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.

SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP
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Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

Most Important Symptoms and Effects, Both Acute and Delayed

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

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: 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)

SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP
(Hospira Inc.)
Revision date: 03-Aug-2016

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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

SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP
(Hospira Inc.)
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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia PEAK	5 ppm 7.5 mg/m ³
Austria OEL - MAKs	5 ppm 8 mg/m ³
Belgium OEL - TWA	5 ppm 8 mg/m ³
Bulgaria OEL - TWA	5 ppm 8.0 mg/m ³
Cyprus OEL - TWA	5 ppm 8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³
Estonia OEL - TWA	5 ppm 8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m ³
Germany (DFG) - MAK	2 ppm 3.0 mg/m ³
Greece OEL - TWA	5 ppm 7 mg/m ³
Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm 8 mg/m ³
Italy OEL - TWA	5 ppm 8 mg/m ³
Japan - OELs - Ceilings	2 ppm 3.0 mg/m ³
Latvia OEL - TWA	5 ppm 8 mg/m ³
Lithuania OEL - TWA	5 ppm 8 mg/m ³
Luxembourg OEL - TWA	5 ppm 8 mg/m ³
Malta OEL - TWA	5 ppm 8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 ppm 8 mg/m ³
Romania OEL - TWA	5 ppm 8 mg/m ³
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	5 ppm 8 mg/m ³
Spain OEL - TWA	5 ppm 7.6 mg/m ³
Switzerland OEL - TWAs	2 ppm 3.0 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³
Sodium hydroxide	
ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³

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Material Name: Ketorolac Tromethamine Injection, USP
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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.

SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP
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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

Flammability:

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 No data available

Products:

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.

SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP
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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/m³
 Rat Oral LD50 7,060mg/kg
 Mouse Inhalation LC50 4h 39g/m³
 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 Oral 16 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

SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP
(Hospira Inc.)
Revision date: 03-Aug-2016

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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	
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	NPDES	LC50	96 Hours	12,900 mg/L	
<i>Pimephales promelas</i> (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

SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP
(Hospira Inc.)
Revision date: 03-Aug-2016

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13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

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

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

SAFETY DATA SHEET

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

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
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

SAFETY DATA SHEET

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

Revision date: 27-Jul-2017

Version: 1.0

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

Product Identifier

Material Name: Lidocaine hydrochloride and epinephrine injection, solution (Hospira, Inc.)

Trade Name: Not established
Synonyms: Lignocaine with epinephrine
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product anesthetic agent

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
 275 North Field Drive
 Lake Forest, Illinois 60045
 1-800-879-3477

Hospira UK Limited

Horizon

Honey Lane

Hurley

Maidenhead, SL6 6RJ

United Kingdom

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

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

Note:

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

SAFETY DATA SHEET

Material Name: Lidocaine hydrochloride and epinephrine
injection, solution (Hospira, Inc.)
Revision date: 27-Jul-2017

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Epinephrine	51-43-4	200-098-7	Acute Tox. 2 (H300) Acute Tox. 2 (H310)	<= 0.002
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
Lidocaine Hydrochloride	73-78-9	200-803-8	Acute Tox.4 (H302)	<= 2
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**
Sodium metabisulfite USP	7681-57-4	231-673-0	Acute Tox. 4 (H302) Eye Dam. 1 (H318)	<0.1

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

Additional Information:

* Proprietary

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

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

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

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

Skin Contact:

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

Ingestion:

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

Inhalation:

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

Most Important Symptoms and Effects, Both Acute and Delayed**Symptoms and Effects of Exposure:**

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions

None known

Aggravated by Exposure:**Indication of the Immediate Medical Attention and Special Treatment Needed****Notes to Physician:**

None

5. FIRE FIGHTING MEASURES**Extinguishing Media:**

Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters

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

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

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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

Additional Consideration for Large Spills: Contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal.

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

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

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

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

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

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m ³
Austria OEL - MAKs	5 ppm
	8 mg/m ³
Belgium OEL - TWA	5 ppm
	8 mg/m ³
Bulgaria OEL - TWA	5 ppm
	8.0 mg/m ³
Cyprus OEL - TWA	5 ppm
	8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Estonia OEL - TWA	5 ppm 8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m ³
Germany (DFG) - MAK	2 ppm 3.0 mg/m ³
Greece OEL - TWA	5 ppm 7 mg/m ³
Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm 8 mg/m ³
Italy OEL - TWA	5 ppm 8 mg/m ³
Japan - OELs - Ceilings	2 ppm 3.0 mg/m ³
Latvia OEL - TWA	5 ppm 8 mg/m ³
Lithuania OEL - TWA	5 ppm 8 mg/m ³
Luxembourg OEL - TWA	5 ppm 8 mg/m ³
Malta OEL - TWA	5 ppm 8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 ppm 8 mg/m ³
Romania OEL - TWA	5 ppm 8 mg/m ³
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	5 ppm 8 mg/m ³
Spain OEL - TWA	5 ppm 7.6 mg/m ³
Switzerland OEL - TWAs	2 ppm 3.0 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³
Sodium chloride	
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
SODIUM HYDROXIDE	
ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Switzerland OEL - TWAs	2 mg/m ³

Sodium metabisulfite USP

ACGIH Threshold Limit Value (TWA)	5 mg/m ³
Australia TWA	5 mg/m ³
Belgium OEL - TWA	5 mg/m ³
Denmark OEL - TWA	5 mg/m ³
France OEL - TWA	5 mg/m ³
Greece OEL - TWA	5 mg/m ³
Ireland OEL - TWAs	5 mg/m ³
Portugal OEL - TWA	5 mg/m ³
Spain OEL - TWA	5 mg/m ³
Switzerland OEL - TWAs	5 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³

Epinephrine

Pfizer Occupational Exposure Band (OEB): OEB 4 - Skin (control exposure to the range of 1ug/m³ to <10ug/m³, provide additional precautions to protect from skin contact)

Lidocaine Hydrochloride

Pfizer Occupational Exposure Band (OEB): OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Sodium chloride

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

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands:	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Clear, colorless
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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

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

Water for injection

No data available

Sodium chloride

No data available

Sodium metabisulfite USP

No data available

SODIUM HYDROXIDE

No data available

HYDROCHLORIC ACID

No data available

Epinephrine

No data available

Lidocaine Hydrochloride

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	

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10. STABILITY AND REACTIVITY

Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

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

There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

Short Term:

Harmful if swallowed. May cause mild eye irritation. May cause slight skin irritation. (based on components) Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

Known Clinical Effects:

Adverse effects associated with therapeutic use include dizziness, nervousness, agitation, drowsiness, apprehension, euphoria, blurred/double vision, slurred speech, tremors, convulsions, and seizure. Respiratory depression and arrest may follow. Other, more serious effects seen with IV use of this drug, particularly when it is administered rapidly, are cardiovascular collapse, central nervous system depression, and/or hypotension.

Acute Toxicity: (Species, Route, End Point, Dose)**Sodium chloride**

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

HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

Epinephrine

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

Lidocaine Hydrochloride

Rat Oral LD50 317 mg/kg
Rat Para-periosteal LD50 25mg/kg
Rat Intraperitoneal LD50 133mg/kg
Mouse Oral LD50 292mg/kg
Mouse Intravenous LD50 19.5mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)**Sodium chloride**

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Lidocaine Hydrochloride

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

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11. TOXICOLOGICAL INFORMATION**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))****Epinephrine**

Embryo / Fetal Development	Rat	Intravenous	Dose not specified	Not teratogenic	
Embryo / Fetal Development	Rabbit	Subcutaneous	30 times human dose	LOAEL	Developmental toxicity
Embryo / Fetal Development	Mouse	Subcutaneous	7 times human dose	LOAEL	Developmental toxicity

Lidocaine Hydrochloride

Embryo / Fetal Development	Rat	Subcutaneous	30 mg/kg	NOAEL	Not teratogenic
Embryo / Fetal Development	Rat	Intraperitoneal	56 mg/kg	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Intraperitoneal	72 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Intravenous	500 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Intraperitoneal	6 mg/kg	LOAEL	Developmental toxicity

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

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vivo</i> Micronucleus	Rat	Negative

Epinephrine

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Sister Chromatid Exchange	Negative with activation	
Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Equivocal without activation

Lidocaine Hydrochloride

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative

Carcinogen Status:

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

Sodium metabisulfite USP

IARC:	Group 3 (Not Classifiable)

HYDROCHLORIC ACID

IARC:	Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:	No data available

Persistence and Degradability:	No data available

Bio-accumulative Potential:	No data available

Mobility in Soil:	No data available

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13. DISPOSAL CONSIDERATIONS

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

Epinephrine
 RCRA - P Series Wastes Listed

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

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

Epinephrine	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3 Schedule 4
EU EINECS/ELINCS List	200-098-7
HYDROCHLORIC ACID	
CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg

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15. REGULATORY INFORMATION

CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	Schedule 6
	231-595-7
Lidocaine Hydrochloride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-803-8
Sodium chloride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3
SODIUM HYDROXIDE	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
California Proposition 65	454 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	215-185-5
Sodium metabisulfite USP	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	
	231-673-0
Water for injection	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	
	231-791-2

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

Acute toxicity, oral-Cat.3; H302 - Harmful if swallowed
Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Acute toxicity, dermal-Cat.2; H310 - Fatal in contact with skin
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation
Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed

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

Reasons for Revision: New data sheet.

Revision date: 27-Jul-2017

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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

End of Safety Data Sheet



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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

Hospira UK Limited

Horizon

Honey Lane

Hurley

Maidenhead, SL6 6RJ

United Kingdom

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

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

Note:

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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

None known

Aggravated by Exposure:

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.

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Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: 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/m³

Lithuania OEL - TWA 5 mg/m³

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit: 2 mg/m³

Australia PEAK 2 mg/m³

Austria OEL - MAKs 2 mg/m³

Bulgaria OEL - TWA 2.0 mg/m³

Czech Republic OEL - TWA 1 mg/m³

Estonia OEL - TWA 1 mg/m³

France OEL - TWA 2 mg/m³

Greece OEL - TWA 2 mg/m³

Hungary OEL - TWA 2 mg/m³

Japan - OELs - Ceilings 2 mg/m³

Latvia OEL - TWA 0.5 mg/m³

OSHA - Final PELs - TWAs: 2 mg/m³

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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

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

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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/m³ to < 1000ug/m³)

Sodium chloride

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

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands:	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
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			

SAFETY DATA SHEET

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

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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

Flammability:

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

Flammability (Solids): No data available

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

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

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

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

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

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

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: 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

SAFETY DATA SHEET

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

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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)

SAFETY DATA SHEET

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

SAFETY DATA SHEET

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15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
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.

SAFETY DATA SHEET

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

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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

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

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

1. IDENTIFICATION

Product Identifier:	Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%
Synonyms:	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate
National Drug Code (NDC):	50383-775-04 50383-775-17
Recommended Use:	Pharmaceutical. Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2% is indicated for the production of topical anesthesia of irritated or inflamed mucous membranes of the mouth and pharynx. It is also useful for reducing gagging during the taking of X-ray pictures and dental impressions.
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:	Specific Target Organ Toxicity – Repeated Exposure	Category 2
Symbol(s):		
Signal Word:	Warning.	
Hazard Statement(s):	H373 May cause damage to organs through prolonged or repeated exposure.	
Precautionary Statement(s):	P260 Do not breathe vapor or spray. P264 Wash hands thoroughly after handling. P314 Get medical attention if you feel unwell.	



SAFETY DATA SHEET

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

P305 IF IN EYES: Rinse cautiously with water for
+ several minutes. Remove contact lenses, if
P351 present and easy to do. Continue rinsing.
+
P338

P337 If eye irritation persists: Get medical attention.
+
P313

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
Lidocaine Hydrochloride	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate	6108-05-0	C ₁₄ H ₂₂ N ₂ O	234.34	2%

The formula also contains the following inactive ingredients: Carboxymethylcellulose Sodium, Methylparaben, Natural Orange Flavor, Propylparaben, Purified Water, and Saccharin Sodium. The pH is adjusted to 5.0 to 7.0 by means of Hydrochloric Acid and/or Sodium Hydroxide.

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.



SAFETY DATA SHEET

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

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:

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. 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.

**Medical Conditions Aggravated
by Exposure:**

As with all pharmaceuticals, hypersensitivity is possible.

Notes to Physician:

Treat supportively and symptomatically. Excessive dosage, or short intervals between doses, can result in high plasma levels and serious adverse effects. Patients should be instructed to strictly adhere to the recommended dosage and administration guidelines as set forth in the package insert. The management of serious adverse reactions may require the use of



SAFETY DATA SHEET

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

resuscitative equipment, oxygen and other resuscitative drugs.

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: Store at 15° to 30°C (59° to 86°F) Shake well before use. Store according to label and/or product insert information.

Specific End Use: Pharmaceutical drug product.



SAFETY DATA SHEET

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Lidocaine 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:

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.



SAFETY DATA SHEET

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	Clear, viscous solution.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	5.0 to 7.0.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	>150°F.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	>1.
Relative Density:	Approximately that of water.
Solubility(ies):	Very soluble in water and alcohol; soluble in chloroform; insoluble in ether.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. STABILITY AND REACTIVITY

Reactivity:	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):	Contact with incompatible materials.
Incompatible Materials:	Strongly alkaline conditions. Methyl vinyl ether; zinc.
Hazardous Decomposition Products:	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.



SAFETY DATA SHEET

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation: No data available.

Ingestion: Harmful if swallowed.

Skin Contact: No data available.

Eye Contact: No data available.

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
Lidocaine Hydrochloride	Mouse	Oral	LD ₅₀	292 mg/kg
Lidocaine Hydrochloride	Rat	Oral	LD ₅₀	159-324 mg/kg

Irritation / Sensitization

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

Repeated Dose 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



SAFETY DATA SHEET

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
Lidocaine Hydrochloride	Ames Test	S. typhimurium and E. coli	Negative
Lidocaine Hydrochloride	Chromosomal aberration assay	Human lymphocytes	Negative
Lidocaine Hydrochloride	<i>In Vivo</i> micronucleus assay	Mouse	Negative

Aspiration Hazard:	None anticipated from normal handling of this product.
Toxicokinetics/Metabolism:	See package insert for more information.
Target Organ Effects:	Based on clinical use, possible target organs include the nervous system and cardiovascular system.
Reproductive Effects:	Pregnancy Category B. Reproduction studies have been performed in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine.
Carcinogenicity:	Studies of lidocaine in animals to evaluate the carcinogenic potential have not been conducted.
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
Lidocaine Hydrochloride	Daphnia magna	EC ₅₀	112 mg/l	48 hours
Lidocaine Hydrochloride	Zebra danio (Danio rerio)	LC ₅₀	106 mg/l	96 hours

Terrestrial Toxicity:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.



SAFETY DATA SHEET

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

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
Lidocaine 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



SAFETY DATA SHEET

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Lidocaine Hydrochloride	Listed	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.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

SAFETY DATA SHEET

LYSOL® IC™ Brand III Disinfectant Spray



1. Product and company identification

Product name : LYSOL® IC™ Brand III Disinfectant Spray

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.
 Professional use

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 # : D0313648 v6.0

Formulation #: : 1589-023 (0271639 v1.0)

EPA ID No. : 777-99-675

UPC Code / Sizes : 36241-95029-08 (19 oz. Aerosol Can)

2. Hazards identification

Classification of the substance or mixture : FLAMMABLE AEROSOLS - Category 2
 GASES UNDER PRESSURE - Liquefied gas
 Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 2.4%

GHS label elements

Hazard pictograms :



Code # : FF0271639
 (D0313648)

SDS # : D0313648 v6.0

Date of issue : 22/08/2016.

1/14

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0313648 v6.0

2. Hazards identification

Signal word	: Warning
Hazard statements	: Flammable aerosol. Contains gas under pressure; may explode if heated.
<u>Precautionary statements</u>	
General	: Read label before use. 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. Store in a well-ventilated place.
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.
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.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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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** : 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.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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5. Fire-fighting measures

Hazardous thermal decomposition products

- : Decomposition products may include the following materials:
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.

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.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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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. Protect from sunlight. Eliminate all ignition sources. Use appropriate containment to avoid environmental contamination.

8. Exposure controls/personal protection

Control

Occupational exposure limits

Ingredient name	Exposure limits
Ethyl alcohol	ACGIH TLV (United States, 6/2013). STEL: 1000 ppm 15 minutes. OSHA PEL 1989 (United States, 3/1989). TWA: 1000 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours. NIOSH REL (United States, 10/2013). TWA: 1000 ppm 10 hours. TWA: 1900 mg/m ³ 10 hours. OSHA PEL (United States, 2/2013). TWA: 1000 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours.
butane	OSHA PEL 1989 (United States, 3/1989). TWA: 800 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours. NIOSH REL (United States, 10/2013). TWA: 800 ppm 10 hours. TWA: 1900 mg/m ³ 10 hours. ACGIH TLV (United States, 6/2013). STEL: 1000 ppm 15 minutes.
propane	OSHA PEL 1989 (United States, 3/1989). TWA: 1000 ppm 8 hours. TWA: 1800 mg/m ³ 8 hours. NIOSH REL (United States, 10/2013). TWA: 1000 ppm 10 hours. TWA: 1800 mg/m ³ 10 hours. OSHA PEL (United States, 2/2013). TWA: 1000 ppm 8 hours. TWA: 1800 mg/m ³ 8 hours.

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8. Exposure controls/personal protection

- 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.

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9. Physical and chemical properties

Flash point	: Closed cup: 25.6°C (78.1°F)
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: 0.8667 to 0.8967 g/cm ³ [20 to 25°C]
Solubility	: Easily soluble in the following materials: cold water and hot water.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.

Aerosol product

Type of aerosol	: Spray
Heat of combustion	: 17.99 kJ/g
Ignition distance	: <45.72 cm

10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	: Avoid all possible sources of ignition (spark or flame).
Incompatible materials	: Do not mix with household chemicals.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Ethyl alcohol	LC50 Inhalation Vapor	Rat	124700 mg/m ³	4 hours
	LD50 Oral	Rat	7 g/kg	-
*Professional Lysol® Brand Kills 99.9% of Viruses and Bacteria** I.C.TM Disinfectant Spray Hospital Disinfectant	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

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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11. Toxicological information

Product/ingredient name	Result	Species	Score	Exposure	Observation
Ethyl alcohol *Professional Lysol® Brand Kills 99.9% of Viruses and Bacteria** I.C.TM Disinfectant Spray Hospital Disinfectant	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	-
	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

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.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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11. Toxicological information

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.
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.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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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.

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

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14. Transport information

Mexico Classification	UN1950	Aerosols, flammable	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; 2-(4-tert-butylbenzyl)propionaldehyde
TSCA 8(a) CDR Exempt/Partial exemption: Not determined
United States inventory (TSCA 8b): Not determined.
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.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Fire hazard
Sudden release of pressure

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

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15. Regulatory information

- 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

Canada

- WHMIS (Canada)** : Class B-2: Flammable liquid
Class B-5: Flammable aerosol.

Canadian lists

- Canadian NPRI** : The following components are listed: Ethanol; Butane (all isomers); Propane
- CEPA Toxic substances** : None of the components are listed.
- Canada inventory** : Not determined.

Label elements

- Signal word:** : CAUTION
- Hazard statements** : Causes moderate eye irritation
- Precautionary measures** : Do not get in eyes, on skin or on clothing. Wash thoroughly after handling. Wash with soap and water.
Keep out of the reach of children.
CONTENTS UNDER PRESSURE. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120 °F. Keep away from heat, sparks, open flames and hot surfaces. - No smoking.

Hazard statements :



Flammable

16. Other information

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

Health	1
Flammability	3
Physical hazards	0
Personal protection	B

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings are not required on MSDSs under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

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

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16. Other information



NFPA (30B) aerosol Flammability Level 1

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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

Key to abbreviations

: ATE = Acute Toxicity Estimate
 BCF = Bioconcentration Factor
 GHS = Globally Harmonized System of Classification and Labelling of Chemicals
 IATA = International Air Transport Association
 IBC = Intermediate Bulk Container
 IMDG = International Maritime Dangerous Goods
 LogPow = logarithm of the octanol/water partition coefficient
 MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
 UN = United Nations

Date of issue : 22/08/2016.

Date of previous issue : 26/06/2015.

Version : 6

Prepared by : Reckitt Benckiser LLC.
 Product Safety Department
 1 Philips Parkway
 Montvale, New Jersey 07646-1810 USA.
 FAX: 201-476-7770

Revision comments : Change in product Brand name.

▣ Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

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16. Other information



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



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.

Product Name: MARCAINE - Bupivacaine Hydrochloride Injection**3. COMPOSITION/INFORMATION ON INGREDIENTS**

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

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.

Product Name: MARCAINE - Bupivacaine Hydrochloride Injection



8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure Limits			
	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

Product Name: MARCAINE - Bupivacaine Hydrochloride Injection**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	mg/kg	Rat
				6.1	mg/kg	Mouse
				3.4	mg/kg	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.

Product Name: MARCAINE - Bupivacaine Hydrochloride Injection



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.

Product Name: MARCAINE - Bupivacaine Hydrochloride Injection



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.

Product Name: MARCAINE - Bupivacaine Hydrochloride Injection



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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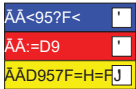
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This safety data sheet complies with the requirements of 29CFR1910.1200.

1.0 IDENTIFICATION

PRODUCT NAME: McKesson Alcohol Prep Pads

MFR #: 58-204, 58-404, 16-527, 16-528

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

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

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

PRODUCT DESCRIPTION: McKesson Alcohol Prep Pads

2.0 HAZARDS IDENTIFICATION

CLASSIFICATION

OSHA Regulatory Status

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

Physical Hazards

Health Hazards

Environmental Hazards

OSHA defined hazards

Flammable Solids

Serious eye damage/eye irritation Category 2A

Not determined

None additional

Label Elements

Pictograms



Signal Word

Danger



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Hazard Statements

Flammable solid.

Causes serious eye irritation.

Precautionary Statements – Prevention

Keep away from heat/spark/open flames/hot surfaces.

No smoking.

Use only in a well ventilated area.

Precautionary Statements – Response

If case of fire: use appropriate media to extinguish.

If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing. Immediately call a poison control center.

If inhaled: remove victim to fresh air and keep comfortable for breathing.

Precautionary Statement – Disposal

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

Hazards not otherwise classified (HNOC)

Not applicable

Other information

Not know.

3.0 COMPOSITION/INFORMATION ON INGREDIENTS**Synonyms**

None

Substance: Mixture

CHEMICAL NAME	CAS NO.	WEIGHT (%)
Isopropyl Alcohol	67-63-0	70
Purified Water	7732-18-5	30

4.0 FIRST AID MEASURES**DESCRIPTION OF FIRST AID MEASURES****General Advice**

Keep victim warm and quiet. Monitor for systemic secondary effects on liver and kidney. Ensure that medical personnel are aware of the material (s) involved and take precautions to protect themselves.



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Eye Contact	Immediately flush with plenty of water. After initial flushing remove any contact lenses and continue flushing for at least 15 minutes. Seek immediate medical attention/advice.
Skin Contact	In case of skin irritation, discontinue use of product. Wash off with soap and water. Get medical attention if irritation develops and persists.
Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Ingestion	If swallowed, contact a Poison Control Center immediately. Immediately rinse mouth out with water. Do not induce vomiting. If vomiting occurs naturally, have victim lean forward to reduce risk of aspiration. Never give anything by mouth if victim is unconscious or is convulsing.

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Symptoms	May include stinging, tearing, redness, swelling and blurred vision.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

Provide general supportive measures and treat asymptotically.

5.0 FIRE-FIGHTING MEASURES

SUITABLE EXTINGUISHING MEDIA

Use foam, dry chemical or carbon dioxide. Be aware of possibility of re-ignition. Keep containers and surroundings cool with water spray.

Unsuitable extinguishing media:	None

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

During fire, gases hazardous to health may be formed.

Explosion data	
Sensitivity to Mechanical Impact	None
Sensitivity to Static Discharge	None



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PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots and in enclosed spaces, SCBA. Structural firefighters protective clothing will only provide limited protection.

In case of fire or explosion, do not breathe fumes. In the event of fire, use water spray to cool fire exposed surfaces and to protect personnel. Shut off fuel to the fire. If a leak or spill has not ignited, use water spray to disperse the vapors.

6.0 ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Personal Precautions	Wear appropriate protective equipment and clothing during clean up.

Other Information	Eliminate all sources of ignition.

For Emergency Responders	Use personal protective equipment as required. Vapors can accumulate in low areas. Consider need for evacuation.

<u>ENVIRONMENTAL PRECAUTIONS</u>	Collect spillage. Prevent material from entering water courses.

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Methods for Containment	Contain and absorb using earth, sand or inert materials. Transfer into suitable containers for recovery or disposal.

Methods for Cleaning up	N/A

7.0 HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Advice on Safe Handling	Do not handle near open flame or heat sources. Do not use with electrocautery procedures. Use according to package label instructions. Discard after single use. Avoid inhaling vapor and contact with eyes.



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CONDITIONS FOR SAFE STORAGE**Storage Conditions**

Keep container closed. Store in a cool, dry, well ventilated place. Keep away from sources of ignition.

Incompatible Materials

N/A

8.0 EXPOSURE CONTROLS/PERSONAL PROTECTION

CONTROL PARAMETERS**Exposure Guidelines**

OSHA PEL Limits for Air contaminants

Isopropanol 980 mg/m³, 400 ppm

US ACGIH Threshold Limit Values

Isopropanol STEL 400 ppm

Isopropanol TWA 200 ppm

US NIOSH

Isopropanol STEL 1225 mg/m³, 500 ppm

Isopropanol TWA 980 mg/m³, 400 ppm

Biological Limit Values

ACGIH Biological Exposure Indices

Isopropanol

40mg/l, Acetone, Urine

APPROPRIATE ENGINEERING CONTROLS

Ventilation systems. Eyewash stations. Showers.

INDIVIDUAL PROTECTION MEASURES, SUCH AS PPE**Eye/Face Protection**

Wear gear deemed necessary.

Skin and Body Protection

Wear gear as deemed necessary.

Respiratory Protection

Wear positive pressure self contained breathing apparatus (SCBA)

General Hygiene Considerations

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the product. When using, do not smoke. When using do not eat or drink.

9.0 PHYSICAL AND CHEMICAL PROPERTIES



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INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Physical State	Liquid
Appearance	Clear, Colorless
Form	Pre-moistened towelette
Color	N/A
Odor	Alcohol odor
Odor Threshold	No information available

Property	Values	Remarks
pH (1-3% aqueous solution)	Not applicable	
Melting point/freezing point	- C	
Boiling point/boiling range	Between 82 and 83 C	
Flash point	12 C	
Evaporation rate	2.5	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air - Upper flammability limit - Lower flammability limit	LEL/UEL 2.0/12.7 vol %	Not Flammable
Vapor pressure	33 mmHg	
Vapor density	Not applicable	
Specific Gravity	0.785	
Water solubility	Not applicable	
Solubility in water	100%	
Partition coefficient	Not applicable	
Autoignition temperature	399 C	
Decomposition temperature	Not applicable	
Kinematic viscosity	Not applicable	
Dynamic viscosity	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	
Softening point	Not applicable	
Molecular weight	Not applicable	
VOC Content (%)	Not applicable	
Density	Not applicable	
Bulk Density	0.9g/cc	

10.0 STABILITY AND REACTIVITY**CHEMICAL STABILITY**

Stable under normal condition of handling, use and transport.

POSSIBILITY OF HAZARDOUS REACTIONS

None under normal processing.

Hazardous polymerization

Does not occur.



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CONDITIONS TO AVOID

Heat, flames and sparks. Avoid temperatures exceeding flash point.

INCOMPATIBLE MATERIALS

Strong oxidizing agents.

HAZARDOUS DECOMPOSITION PRODUCTS

May include but are not limited to oxides of carbon.

11.0 TOXICOLOGICAL INFORMATION**INFORMATION ON LIKELY ROUTES OF EXPOSURE****Product Information**

Available toxicological data for individual ingredients are summarized below.

Inhalation

Vapors have a narcotic effect and may cause headache, fatigue, dizziness and nausea. Health injuries are not known or expected under normal use.

Eye Contact

Causes serious eye irritation.

Skin Contact

Not expected to be a primary skin irritant.

Ingestion

Not applicable under normal conditions of use.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LD50
Isopropanol 67-63-0	5045 mg/kg (rat)	Eye 12800 mg/kg (rabbit)	16970 mg/l/4h

INFORMATION ON TOXICOLOGICAL EFFECTS

No information available.

DELAYED AND IMMEDIATE EFFECTS AS WELL AS CHRONIC EFFECTS FROM SHORT AND LONG-TERM EXPOSURE**Skin corrosion/irritation**

Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation

Causes serious irritation to the eye

Respiratory or skin sensitization

Not expected to cause skin sensitization.

Sensitization

No sensitization responses were observed.

Germ cell mutagenicity

Not expected to have chronic health effects.

Carcinogenicity

This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC, ACGHI or NTP.

US OSHA Specifically Regulated Substances Not listed

Reproductivity Toxicity

Finished product not expected to have chronic health effects.

STOT- single exposure

Narcotic effects.

STOT – repeated exposure

Not classified.

Chronic Toxicity

No known effect.

Sub-chronic Toxicity

No known effect.

Neurological Effects

Not applicable.



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NUMERICAL MEASURES OF TOXICITY

Not available.

12.0 ECOLOGICAL INFORMATION**ECOTOXICITY**

Chemical Name	Algae/Aquatic Plants	Fish	Crustacea
Isopropanol 67-63-0	IC 50 100mg/L, 72 hours	LC 50 Bluegill > 1400 ml/l, 96 hours	EC 50 13299 mg/L: 72 h Daphnia magna

Persistence and degradability

No data available.

Bioaccumulation

No data available.

Partition coefficient n-octanol/water (log Kow) Isopropanol 0.05

Mobility

No data available.

Other adverse effects

None expected.

13.0 DISPOSAL CONSIDERATIONS**WASTE TREATMENT METHODS****DISPOSAL OF WASTE**

Disposal should be in accordance with applicable regional, national and local laws and regulations. Dispose of contents/containers in accordance with local regulations. This material, as supplied, is not a hazardous waste according to state and federal regulations (40 CFR 61).

Contaminated packaging

Following warning label.

State of California Hazardous Waste Status

Isopropanol (67-63-0) Listed

14.0 TRANSPORT INFORMATION**NOTE: THIS MATERIAL IS NOT SUBJECT TO REGULATION AS A DANGEROUS GOOD.****DOT**

Not regulated

TDG

Not regulated

MEX

Not regulated

ICAO

Not regulated

IATA

Not regulated

IMDG

Not regulated

RID

Not regulated

ADR

Not regulated. European requirement only.



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AND

Not regulated. European requirement only.

15.0 REGULATORY INFORMATION

INTERNATIONAL INVENTORIES

OSHA Specifically regulated substances Not listed

LEGEND

TSCA – United States Toxic Substances Control Act Section 8b Inventory

DSL/NDL – Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS – European Inventory of Existing chemical Substances/European List of Notified Chemical

ENCS – Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS – Phillipines Inventory of Chemicals and Chemical Substances

AICS – Australian Inventory of Chemical Substances

US FEDERAL REGULATION

SARA

Hazard categories	Immediate Hazard – Yes
	Delayed Hazard – No
	Fire Hazard – Yes
	Pressure Hazard – No
	Reactivity Hazard - No

SARA 302 Extremely Hazardous Substances No

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

SARA 313 (TRI Reporting)

Isopropanol (67-63-0)	40-70% by weight

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).



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FDA Regulated as a drug.

CERCLA Isopropanol (67-63-0) Listed

US STATE REGULATIONS

CALIFORNIA PROPOSITION 65

This product does not contain any Proposition 65 chemicals.

US RIGHT TO KNOW REGULATIONS

Isopropanol (67-63-0) Listed California (Hazardous Substances (Director's), Illinois, Louisiana, Minnesota, New Jersey, Massachusetts, Pennsylvania, Rhode Island

Country(s) of Origin United States & Puerto Rico

Toxic Substances Control Act (TSCA) Inventory On inventory? Yes

US EPA LABEL INFORMATION

Not applicable.

16.0 OTHER INFORMATION

NFPA

Health Hazards	1
Flammability	3
Reactivity/Instability	0

HMIS

Health Hazards	1
Flammability	3
Physical Hazards	0
Personal Protection	X

Prepared by

Cypress Medical Products, LLC Quality Assurance

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of 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



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information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

---End of Document---



SDS DATE: 9/18/2015

* SAFETY DATA SHEET *

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: McKesson Antimicrobial Soap Clean Scent
MFR #: 53-28071-GL, 53-28073-8, 53-28076-1000, 53-28077-18

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

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

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

PRODUCT DESCRIPTION: A surfactant blended antibacterial hand soap for hand washing to decrease bacteria on the skin.

2. HAZARDS IDENTIFICATION

Appearance clear viscous orange liquid

Physical State Liquid

Odor Pleasant

Classification

This chemical does not meet the hazardous criteria set forth by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). However, this Safety Data Sheet (SDS) contains valuable information critical to the safe handling and proper use of this product. This SDS should be retained and available for employees and other users of this product.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

Surfactant blend.

4. FIRST-AID MEASURES

First Aid Measures

General Advice	Provide this SDS to medical personnel for treatment. Always get medical attention when product is swallowed or when symptoms are significant or persist.
Eye Contact	Flush with water for 15 minutes. If irritation persists, call physician.
Skin Contact	Wash liberally with soap and water. If on clothes: Wash before reuse.
Inhalation	Not an expected route of exposure.
Ingestion	If patient is conscious and alert, dilute by drinking large quantities of water. Allow vomiting to occur if patient is conscious and alert, then get medical attention.



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Most important symptoms and effects

Symptoms	If in eyes: Burning sensation, watering, or redness. If swallowed: Possible gastrointestinal irritation or disturbance.

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 Not determined.

Specific Hazards Arising from the Chemical

This is a water based non-flammable product with no known fire or explosion hazards.

Hazardous Combustion Products Carbon oxides.

Protective equipment and precautions for firefighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions	Use personal protective equipment as required.

Methods and material for containment and cleaning up

Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for Clean-Up	SMALL SPILLS: Small spills (< 1 gallon) may be washed down a drain or cleaned up and disposed of into a sanitary sewer system. LARGE SPILLS: Large spills (> 1 gallon) should be contained and collected (by absorption or vacuuming) then disposed of properly.



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7. HANDLING AND STORAGE

Precautions for safe handling

Advice on Safe Handling Handle in accordance with good industrial hygiene and safety practice. Do not contaminate water, food, or feed. Do not reuse empty containers. Keep containers clean & closed.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep out of the reach of children.

Incompatible Materials None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines The following information is given as general guidance

Appropriate engineering controls

Engineering Controls Mechanical Ventilations (General): Normally sufficient
Local Exhaust: Not Normally Needed.

Individual protection measures, such as personal protective equipment

Eye/Face Protection Not normally required under normal use conditions. Avoid eye contact when using.

Skin and Body Protection NOT NEEDED, this product is a skin cleaner.

Respiratory Protection Not needed. General ventilation is normally adequate.

General Hygiene Considerations Do not get into eyes. Protect food & drink from contamination by product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid	Odor	Pleasant
Appearance	clear viscous orange liquid	Odor Threshold	Not determined
Color	Clear orange		
<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>	
pH	6.00-7.00		
Melting Point/Freezing Point	Not established		
Boiling Point/Boiling Range	100 °C / 212 °F		
Flash Point	Not determined		
Evaporation Rate	Not established		
Flammability (Solid, Gas)	Not determined		
Upper Flammability Limits	Not available		
Lower Flammability Limit	Not available		



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Vapor Pressure	Not established
Vapor Density	Not established
Specific Gravity	.991 – 1.039
Water Solubility	Completely soluble
Solubility in other solvents	Not determined
Partition Coefficient	Not determined
Auto-ignition Temperature	Not determined
Decomposition Temperature	Not determined
Kinematic Viscosity	Not determined
Dynamic Viscosity	2000 to 4000 cps
Explosive Properties	Not determined
Oxidizing Properties	Not determined
Density	8.26-8.66 lbs/gal

10. STABILITY AND REACTIVITY

Reactivity

Not reactive under normal conditions.

Chemical Stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to Avoid

Keep out of reach of children.

Incompatible Materials

None known based on information supplied.

Hazardous Decomposition Products

Carbon dioxide (CO₂), Sulfur dioxide.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Eye Contact

May cause mild eye irritation.

Skin Contact

None, this product is a skin cleaner.

Inhalation

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

Ingestion

Possible gastrointestinal irritation or disturbance.

Component Information

Information on physical, chemical and toxicological effects

Symptoms

Please see section 4 of this SDS for symptoms.



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

Carcinogenicity

This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.

Numerical measures of toxicity

Not determined

12. ECOLOGICAL INFORMATION

Ecotoxicity

The product is not expected to be hazardous to the environment.

Persistence/Degradability

Not determined

Bioaccumulation

Not determined

Mobility

Not determined

Other Adverse Effects

Not determined

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods

Disposal of Wastes

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

Contaminated Packaging

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

14. TRANSPORT INFORMATION

Note

Please see current shipping paper for most up to date shipping information, including exemptions and special circumstances.

DOT

Not regulated

IATA

Not regulated

IMDG

Not regulated



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15. REGULATORY INFORMATION

International Inventories

Not determined

Legend:

*TSCA - United States Toxic Substances Control Act Section 8(b) Inventory**DSL/NDL - 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*

US Federal Regulations

SARA 313

Not determined

US State Regulations

U.S. State Right-to-Know Regulations

Not determined

16. OTHER INFORMATION

NEPA

Health Hazards

0

Flammability

0

Instability

0

Special Hazards

Not determined

HMIS

Health Hazards

0

Flammability

0

Physical Hazards

0

Personal Protection

Not determined



SDS DATE: 9/18/2015

Issue Date	28-Jul-2009
Revision Date:	18-Sep-2015
Revision Note	New format

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



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This safety data sheet complies with the requirements of 29CFR1910.1200.

1.0 IDENTIFICATION

PRODUCT NAME: McKesson Cold Compress
MFR #: 59-57C, 59-79C, 16-9701, 16-9702, 16-9703

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 Cold Compress

2.0 HAZARDS IDENTIFICATION

CLASSIFICATION

OSHA Regulatory Status

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

Classifications

Oxidizing Solid	Category 3
Eye Irritation	Category 2

Label Elements

Pictograms



Signal Word

Warning

Hazard Statements – Chemical from damages, un-activated cold pack may have the following hazards:

May intensify fire; oxidizer

Causes serious eye irritation if contacted.

May be harmful if inhaled or swallowed.

May cause headache, nausea, dizziness and other symptoms of central nervous system depression.



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Contains material which may cause adverse blood system effects.

Precautionary Statements – Prevention

Keep away from heat/sparks/open flames/hot surfaces.

Store away from combustible materials.

Use personal protective equipment as required.

Wash face, hands and exposed skin thoroughly after handling.

Precautionary Statements – Response

If exposed or concerned: get medical attention.

If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

If inhaled: remove victim to fresh air and keep at rest in a position comfortable for breathing.

If swallowed: contact Poison Control or doctor/physician. Rinse mouth.

Precautionary Statement – Disposal

Dispose of contents/container to an approved waste disposal plant.

Hazards not otherwise classified (HNOC)

Not applicable

Other information

- Read entire SDS for more information regarding this product.

3.0 COMPOSITION/INFORMATION ON INGREDIENTS**Synonyms**

N/A

Substance: Mixture

CHEMICAL NAME	CAS NO.	WEIGHT (%)
Ammonium Nitrate	6484-52-2	40-70
Water	7732-18-5	30-60

59-57C and 59-79C only

CHEMICAL NAME	CAS NO.	WEIGHT (%)
Ammonium Nitrate	6484-52-2	Max 78
Magnesium Nitrate	13446-18-9	Not provided
Dolomite	16389-88-1	Not provided



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4.0 FIRST AID MEASURES**DESCRIPTION OF FIRST AID MEASURES****General Advice**

Under conditions of normal use, no hazards are anticipated which require special first aid measures. Get medical attention if any symptoms develop or persist. Always have plenty of water available for first aid.

Eye Contact

Not an expected route of exposure. Chemical from damaged un-activated cold pack may have the following hazards: direct contact may cause slight redness. Chemical from damaged, activated cold pack may have the following hazards: contact with eyes may cause irritation. Symptoms may include: inflammation of eye tissue, characterized by redness, watering and/or itching. Recommended first aid exposure to chemical from damaged cold pack. Immediately flush eyes with plenty of water for at least 15 minutes lifting upper and lower eyelids occasionally. Get medical attention.

Skin Contact

Not an expected route of exposure. Chemical from damaged un-activated cold pack may have the following hazards: may cause mild skin irritation, red, puffy, itchy skin. Chemical from damaged activated cold pack may have the following hazards: prolonged contact may cause numbness, causes little or no irritation. Recommended first aid for exposure to chemical from damaged cold pack: flush with water for at least 15 minutes, while removing contaminated clothing. If irritation occurs or persists, seek medical attention.

Inhalation

Not an expected route of exposure. Chemical from damaged, un-activated cold pack may have the following hazards: inhalation of dust may cause shortness of breath, tightness of chest, a sore throat and cough. Imitating or noxious gases may be released during thermal decomposition. Inhalation of high concentrations may cause unconsciousness and cyanosis. Recommended first aid from chemical from damaged cold pack: immediately remove victim to fresh air. If breathing has stopped, give artificial respiration. If breathing is difficult, give oxygen by qualified medical personnel only. Get medical attention.

Ingestion

Not an expected route of exposure. Harmful effects not expected under normal usage. Chemical from damaged cold



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pack may cause the following hazards: May cause irritation of mouth, throat and stomach. Symptoms may include nausea, vomiting, dizziness, drowsiness and other symptoms of central nervous system depression. Ingestion of large quantities of nitrates may affect oxygen transport in the blood system, causing methemoglobinemia. Large doses can cause shock, convulsions, coma and eventual death. Recommended first aid for exposure to chemical from damaged cold pack: do not induce vomiting. Have victim rinse mouth with water, and then give one to two glasses of water to drink. Never give anything by mouth to an unconscious person.

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Symptoms

Conditions aggravated by overexposure

Harmful effects are not expected under normal usage.

Pre-existing skin, eye and respiratory disorders.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

Note to Physicians

Treat symptomatically. Nitrates in large doses may cause significant vasodilation and hypotension. Pre-existing ischemic heart disease may be aggravated by these effects. In large ingestions, nitrates may cause methemoglobinemia. Methemoglobinemia should be suspected if cyanosis occurs. Methylene blue (1-2mg/kg IV over several minutes) is an effective antidote for symptomatic methemoglobinemia.

5.0 FIRE-FIGHTING MEASURES

SUITABLE EXTINGUISHING MEDIA

Use water spray to fight fires. Use chemical extinguishing agents with caution. Some chemical extinguishing agents may accelerate decomposition.

Unsuitable extinguishing media:

None

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Explosive decomposition may occur under fire conditions. Heat of decomposition may cause closed containers to build up pressure and explode. Chemical from damaged, un-activated cold packs may have the following hazards: strong oxidizer which will promote combustion. Contact with combustible material may cause fire. This product reacts with acids evolving considerable heat.

Explosion data

Sensitivity to Mechanical Impact

None



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Sensitivity to Static Discharge

None

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Fight fires from a safe distance. Evacuate personnel to safe area. Firefighters should wear proper protective equipment and self-contained breathing apparatus with full face piece operated in positive pressure mode. A full-body chemical resistant suit should be worn move containers from fire area if safe to do so. Water spray may be useful in cooling equipment exposed to heat and flame.

6.0 ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES**Personal Precautions**

Ensure clean up is performed by trained personnel only. Keep all other personnel upwind and away from the spill/release. Wear suitable protective equipment.

Other Information

Pick up loose items and place in container for disposal.

For Emergency Responders

Use personal protective equipment as required.

ENVIRONMENTAL PRECAUTIONS

Ensure spilled product does not enter drains, sewers, waterways, or confined spaces.

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP**Methods for Containment**

Collect material for disposal. Do not use combustible absorbents such as sea dust.

Methods for Cleaning up

Ventilate area of release. Remove all sources of ignition. Remove combustible materials. Use only non-combustible absorbent material, such as vermiculite or sand, then place absorbent material into a container for later disposal. Use methods that do not generate dusts. Notify appropriate authorities as required.

7.0 HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING**Advice on Safe Handling**

Use in a well ventilated area. Protect from damage. Keep away from heat and flames. Keep away from combustible



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material. Recommended handling procedures when cold pack damaged: wear suitable protective clothing. Avoid breathing dust, vapor or mist. Do not ingest. Avoid contact with skin, eyes, clothing. Never return material to original container. Label containers appropriately. Wash hands thoroughly after handling.

CONDITIONS FOR SAFE STORAGE

Storage Conditions

Store in a cool dry, well ventilated area. Store away from incompatibles and out of direct sunlight. Inspect periodically for damage and leaks. No smoking in area. Protect from damage.

Incompatible Materials

Acids, reducing agents, combustible materials, organic materials, reactive materials, fuel, halogenated compounds, copper.

8.0 EXPOSURE CONTROLS/PERSONAL PROTECTION

CONTROL PARAMETERS

Exposure Guidelines

Not Available

APPROPRIATE ENGINEERING CONTROLS

Not a hazard under normal conditions of use.

INDIVIDUAL PROTECTION MEASURES, SUCH AS PPE

Eye/Face Protection

Wear safety glasses with side shields (or goggles)

Skin and Body Protection

Gloves impervious to the material are recommended. The suitability for a specific workplace should be discussed with the producers of protective gloves.

Respiratory Protection

Not available

General Hygiene Considerations

Handle in accordance with good industrial hygiene and safety practice. An eyewash station and safety shower should be made available in the immediate working area. Other equipment may be required depending on workplace standard. Avoid contact with skin, eyes and clothing. Avoid breathing vapors, fumes or dust. Do not eat, drink or smoke when using this product. Wash hands before breaks and



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immediately after handling the product. Wear only clean, uncontaminated clothes when leaving place of work.

9.0 PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Physical State	Solid/Liquid
Appearance	Solid in water bag
Color	No data
Odor	None
Odor Threshold	No data available

Property	Values	Remarks
pH (1-3% aqueous solution)	No data available	
Melting point/freezing point	No data available	
Boiling point/boiling range	Not applicable	
Flash point	None	
Evaporation rate	No data available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air - Upper flammability limit - Lower flammability limit	Not applicable	Not Flammable
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific Gravity	1.3	
Water solubility	100%	
Solubility in other solvents	No information available	
Partition coefficient	Not applicable	
Autoignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Kinematic viscosity	Not applicable	
Dynamic viscosity	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	
Softening point	Not applicable	
Molecular weight	Not applicable	
VOC Content (%)	Not applicable	
Density	Not applicable	
Bulk Density	0.9g/cc	

10.0 STABILITY AND REACTIVITY

CHEMICAL STABILITY

Stable under normal condition of handling, use and transport. Chemical from damaged, un-activated cold pack may have the following hazards: strong oxidizer which will promote



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combustion. Contact with combustible material may cause fire.

POSSIBILITY OF HAZARDOUS REACTIONS

None under normal processing.

Hazardous polymerization

Not expected under prescribed storage and handling conditions. Decomposition may occur at extremely high temperatures.

CONDITIONS TO AVOID

Avoid heat and open flame. Ensure adequate ventilation, especially in confined areas. Avoid contact with incompatible materials. Keep out of direct sunlight. Keep away from combustible material. Incompatible materials and dust generation.

INCOMPATIBLE MATERIALS

Avoid contact with reactive, combustible or organic materials such as wood, grain, organic chemicals, acids, corrosive liquids, sulfur, flammable liquids, chlorates, permanganates, finely divided materials, charcoal, coke, cork, or sawdust. Avoid contact with other oxidizers. Contact with alkaline materials may liberate urea.

HAZARDOUS DECOMPOSITION PRODUCTS

Material will not burn, but if involved in a fire, oxides of nitrogen may be generated. Exposure to heat may liberate urea fumes.

11.0 TOXICOLOGICAL INFORMATION

INFORMATION ON LIKELY ROUTES OF EXPOSURE

Product Information

There is no available data for the product itself.

Inhalation

Not available.

Eye Contact

Not available.

Skin Contact

Not available.

Ingestion

Not available.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Ammonium Nitrate 6484-52-2	>2217 mg/kg (rat) 4 h	N/A	> 88800 mg/m3, (rat) 4 h

INFORMATION ON TOXICOLOGICAL EFFECTS

No information available.

DELAYED AND IMMEDIATE EFFECTS AS WELL AS CHRONIC EFFECTS FROM SHORT AND LONG-TERM EXPOSURE

Skin corrosion/irritation

Very slight skin irritation



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Serious eye damage/eye irritation**Irritation****Corrosivity****Sensitization****Germ cell mutagenicity****Carcinogenicity**

Very slight eye irritation

Mild skin irritant. May cause eye irritation.

Not classified.

Not expected to be a skin or respiratory sensitizer.

Not classified.

This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.

Not expected to have other reproductive effects.

Not expected to be mutagenic in humans.

Not expected to be a teratogen.

Not classified.

Not classified.

No known effect.

No known effect.

No known effects under normal conditions.

Not applicable.

Reproductivity Toxicity

Developmental Toxicity

Teratogenicity

STOT- single exposure**STOT – repeated exposure**

Chronic Toxicity

Sub-chronic Toxicity

Target Organ Effects

Neurological Effects

NUMERICAL MEASURES OF TOXICITY

See product information.

12.0 ECOLOGICAL INFORMATION

Environmental effects

This product should not be allowed to enter drains or water courses, or be deposited where it can affect ground or surface water.

Bioaccumulation

No data available

Mobility

No data available

Ecotoxicological

No data available

Other adverse effects

No information available

13.0 DISPOSAL CONSIDERATIONS

WASTE TREATMENT METHODS**DISPOSAL OF WASTE**

Handle waste according to recommendations in section 7.

Empty containers retain residue (liquid and vapor) and can be dangerous. Dispose in accordance with all applicable federal, state, provincial and local regulations. Contact your local,



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state, provincial or federal environmental agency for specific details. If this product as supplied becomes a waste in the United States, it may meet the criteria of a hazardous waste as defined under RCRA, Title 40 CFR261. It is the responsibility of the waste generator to determine the proper waste identification and disposal method.

State of California Hazardous Waste Status

Not applicable

14.0 TRANSPORT INFORMATION

NOTE: THIS MATERIAL IS NOT SUBJECT TO REGULATION AS A HAZARDOUS MATERIAL FOR SHIPPING.

DOT

UN1942, Ammonium Nitrate, Limited Quantity, III
As supplied, this product can be shipped as a limited quantity in the United States. The UN number placed within the square-on-point border appearing here, or the proper shipping name, must appear on the package in accordance with 49 CFR 172.315.

TDG

UN1942, Ammonium Nitrate, 5.1, III
Within Canada only, this product may be shipped according to the 500Kg Gross Mass Exemption. Each means of containment must be marked with either the dangerous goods safety marks required by Part 4 of the Proper shipping name. The dangerous goods must be accompanied by a proper shipping document. Refer to TDG section 1.16 for detailed information on this exemption. If shipping by ground to destinations outside Canada, the limited quantity exemption may be used. Under the TDGR, refer to Section 1.17 for additional exemption information, if shipping under this exemption.

MEX

Not regulated

ICAO

UN1942, Ammonium Nitrate, 5.1, III

IATA

UN1942, Ammonium Nitrate, 5.1, III

Refer to ICAO/IATA pack instruction: Y516, 616 or 518.

Review all state and operator variations, prior to shipping this material.

IMDG

Not regulated

RID

Not regulated

ADR

Not regulated. European requirement only.

AND

Not regulated. European requirement only.

15.0 REGULATORY INFORMATION

INTERNATIONAL INVENTORIES



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TSCA

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

DSL/NDSL

All ingredients listed.

LEGEND

TSCA – United States Toxic Substances Control Act Section 8b Inventory

DSL/NDSL – Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS – European Inventory of Existing chemical Substances/European List of Notified Chemical

ENCS – Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS – Phillipines Inventory of Chemicals and Chemical Substances

AICS – Australian Inventory of Chemical Substances

CEPA – Canadian Environmental Protection Act

US FEDERAL REGULATION

SARA 313

Section 303 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	Immediate

CWA (Clean Water Act)

Data not available

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).

OSHA

This material is not classified as hazardous under OSHA regulation (29CFR Part 1910.1200). This product is considered an “article” under 29 CFR 1910.1200.

US STATE REGULATIONS



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CALIFORNIA PROPOSITION 65

This product does not contain any Proposition 65 chemicals.

NEW JERSEY LABELING REQUIREMENTS

Ammonium Nitrate (6482-52-2)

Water (7732-18-5)

US RIGHT TO KNOW REGULATIONS

Ammonium Nitrate (6484-52-2)

Massachusetts, Rhode Island, Pennsylvania

US EPA LABEL INFORMATION

Not applicable.

16.0 OTHER INFORMATION**NFPA**

Health Hazards	1
Flammability	0
Instability	3
Special Hazards	OX

HMIS

Health Hazards	1
Flammability	0
Reactivity	3
Physical Hazards	Not rated
Personal Protection	Not rated

Prepared by

Cypress Medical Products, LLC Quality Assurance

Disclaimer



SDS DATE: 11/4/2015

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of 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 Document---



SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY INFORMATION

PRODUCT NAME: McKesson Disposable Germicidal Surface Wipes

MFR #: 50-66160, 50-66170

RECOMMENDED USE: Cleaner, Disinfectant, Deodorizer

DISTRIBUTED BY: McKesson Medical-Surgical Inc.

9954 Mayland Drive, Suite 4000

Richmond, VA 23233

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

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

SECTION 2: HAZARDOUS INGREDIENTS

Classification

Hazard Class	Category
Flammable liquid	3
Eye irritation	2A
Specific target organ toxicity (single exposure)	3

Label Elements

Hazard Symbols



Signal Word(s): Warning

Hazard Statement(s): Flammable liquid and vapor. Causes serious eye irritation. May cause drowsiness or dizziness.

Precautionary Statement(s): Keep away from heat/sparks/open flames/hot surfaces. No smoking. Keep container tightly closed. Avoid breathing dust/fume/gas/mist/vapors/spray. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves/eye protection/face protection. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents and container in accordance with all local, regional, national and international regulations.

Other Hazards

1% of the mixture consists of ingredient(s) of unknown acute toxicity.

MCKESSON

SECTION 3: COMPOSITION

Chemical Name	CAS Number	Wt %
Isopropyl alcohol	67-63-0	10-30
2-Butoxyethanol	111-76-2	1-5

The exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of §1910.1200.

SECTION 4: FIRST AID MEASURES

First Aid Measures

Inhalation: Not a normal route of exposure. If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER/doctor/physician if you feel unwell.

Eye Contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses, if worn. If irritation persists, get medical attention.

Ingestion: May result in obstruction and irritation if ingested. If large amounts of liquid are swallowed seek medical attention immediately.

Skin: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Call a physician if irritation develops and persists.

Most Important Symptoms and Effects (Acute and Delayed)

Inhalation: Vapors may cause drowsiness and dizziness. May cause respiratory tract irritation.

Eye Contact: Causes serious eye irritation. Symptoms may include discomfort or pain, excess blinking and tear production, with marked redness and swelling of the conjunctiva.

Ingestion: May be harmful if swallowed. May cause stomach distress, nausea or vomiting.

Skin: May cause skin irritation. Symptoms may include redness, drying, defatting and cracking of the skin.

Indication of any Immediate Medical Attention and Special Treatment Needed

Note to Physician: Treat symptomatically.

SECTION 5: FIRE & EXPLOSION HAZARD DATA

Extinguishing Media

Suitable: Water fog, carbon dioxide, dry chemical or alcohol foam.

Unsuitable: None known.

Specific Hazards Arising from Chemical

Liquid absorbed onto wipe is flammable. Product will burn if exposed to fire. Products of combustion include but are not limited to: oxides of carbon.

Protective Equipment and Precautions for Firefighters

Keep upwind of fire. Wear full fire-fighting turn-out gear (full Bunker gear) and respiratory protection (SCBA).

MCKESSON

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures

Personal Precautions: Use personal protection recommended in Section 8. Isolate the hazard area and deny entry to unnecessary and unprotected personnel. Eliminate sources of ignition.

Environmental Precautions: See Section 12 for ecological information.

Methods and Material for Containment and Cleaning Up

Pick up large pieces, then place in suitable container. Do not flush to sewer or allow to enter waterways. Use appropriate Personal Protective Equipment (PPE). Scoop up material and place in a disposal container. Provide ventilation.

SECTION 7: HANDLING & STORAGE

Precautions for Safe Handling

Handling: Keep away from sources of ignition. No smoking. Take precautionary measures against static discharge. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapors/spray. Do not swallow. Handle and open container with care. When using do not eat, drink or smoke. Use only non-sparking tools. Use only outdoors or in well-ventilated area.

General Hygiene Advice: Launder contaminated clothing before use. Wash hands before eating, drinking, or smoking.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Keep locked up and out of the reach of children. Keep container tightly closed and in a well-ventilated place. Keep cool.

Incompatible Materials: Oxidizers.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Exposure Guidelines:

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Isopropyl alcohol (67-63-0)	200 ppm	980 mg/m ³	Not available
2-Butoxyethanol (111-76-2)	20 ppm	240 mg/m ³	Not available

Appropriate Engineering Controls

Use ventilation adequate to keep exposures (airborne levels of dust, fume, vapor, etc.) below recommended exposure limits.

Individual Protection Measures

Respiratory Protection: In case of insufficient ventilation, wear suitable respiratory equipment. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Skin and Body Protection: Wear suitable protective clothing.

Eye/Face Protection: Safety glasses are recommended when using product.



General Work/Hygienic Practices: Handle in accordance with good industrial hygiene and safety practice. Do not eat, smoke or drink where material is handled, processed or stored. Wash hands carefully before eating or smoking. Handle according to established industrial hygiene and safety practices.

SECTION 9: PHYSICAL/CHEMICAL CHARACTERISTICS

Appearance: Wipes saturated with clear liquid

Odor: Alcohol-like

Odor threshold: Not determined

pH: 7.6 (liquid)

Melting point/freezing point: Not determined

Initial boiling point and boiling range: Not determined

Flash point: 30°C (86°F) TCC (liquid)

Evaporation rate: Not determined

Flammability (solid, gas): Flammable

Upper/lower flammability or explosive limits: Not determined

Vapor pressure: Not determined

Vapor density: Not determined

Relative density: 0.97 (liquid)

Solubility(ies): Not determined

Partition coefficient (n-octanol/water): Not determined

Auto-ignition temperature: Not determined

Decomposition temperature: Not determined

Viscosity: Not determined

SECTION 10: STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions.

Chemical stability: Stable under recommended storage conditions. May form flammable/explosive vapor-air mixture

Possibility of hazardous reactions: None under normal use.

Conditions to avoid: Heat. Incompatible materials. Sources of ignition.

Incompatible materials: Oxidizers.

Hazardous decomposition products: May include and are not limited to: oxides of carbon.



SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Likely Routes of Exposure: Inhalation, skin contact, eye contact, ingestion

Information Related to Physical, Chemical, and Toxicological Effects

See section 4 of this SDS.

Delayed and Immediate Effects as well as Chronic Effects from Short and Long-term Exposure

Carcinogenicity: NTP: No IARC: No OSHA: No

Numerical Measures of Toxicity

Product	
ATE (oral)	>2000 mg/kg, rat
ATE (dermal)	>2000 mg/kg, rabbit
ATE (inhalation)	>20 mg/l/4h

Component Information:

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Isopropyl alcohol (67-63-0)	4396 mg/kg (rat)	12800 mg/kg (rat)	72.6 mg/l/4h
2-Butoxyethanol (111-76-2)	470 mg/kg (rat)	Not available	450 ppm/4h

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: Not established

Persistence and degradability: Not established

Bioaccumulative potential: Not established

Mobility in soil: No additional information available

Other adverse effects: No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

See section 8 of this SDS for exposure controls and personal protection.

Dispose of the product and container in accordance with all applicable local, state, and federal regulations. The generation of waste should be avoided or minimized whenever possible. Handle empty containers with care because residual vapors are flammable.



SECTION 14: TRANSPORT INFORMATION

Note: Classification changes based on quantity, packaging, and method of shipment. See current shipping paper for most up to date shipping information.

DOT (Ground): Not regulated

IATA (Air): Not regulated

IMDG (Vessel): Not regulated

SECTION 15: REGULATORY INFORMATION

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

CAUTION

Harmful if inhaled or absorbed through skin.

Causes moderate eye irritation.

Avoid breathing vapors, and contact with eyes, skin, or clothing.

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

Remove contaminated clothing and wash clothing before reuse.

Do not use or store near heat or open flame.

All ingredients in this product are listed or are excluded from listing on the US Toxic Substances Act (TSCA) Chemical Substance Inventory.

SARA 313

This product contains chemicals which are subject to the reporting requirements of the Superfund Amendments and Reauthorization Act and Title 40 of the Code of Federal Regulations, Part 372. Chemicals: Isopropanol and Butoxyethanol.

SECTION 16: OTHER INFORMATION

Issue Date: 07-Mar-2016

Revision Date: 07-Mar-2016

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



SDS DATE: 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;



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Label elements

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



H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

[Prevention]:

P260 Do not breathe mist / vapors / spray.

P264 Wash thoroughly after handling.

P280 Wear protective gloves / eye protection / face protection.

[Response]:

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

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

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

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

P310 Immediately call a POISON CENTER or doctor / physician.

P363 Wash contaminated clothing before reuse.

[Storage]:

P405 Store locked up.

[Disposal]:

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

SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS

INGREDIENT	CAS NO.	%	Exposure Limits

SECTION 3 NOTES:

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

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



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

SECTION 4: FIRST-AID MEASURES

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

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

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

INHALATION: Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration.
 If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: N/A

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

Most important symptoms and effects, both acute and delayed

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

SECTION 5: FIRE-FIGHTING MEASURES

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

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

AUTOIGNITION TEMPERATURE: N/A

NFPA HAZARD CLASSIFICATION

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

HMIS HAZARD CLASSIFICATION

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

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

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

UNUSUAL FIRE AND EXPLOSION HAZARDS: N/A

HAZARDOUS DECOMPOSITION PRODUCTS: Oxygen which supports combustion.

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

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: N/A

SECTION 6 NOTES:

Personal precautions, protective equipment and emergency procedures

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



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Environmental precautions

Biodegradable, non-hazardous to environment.

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

Methods and material for containment and cleaning up.

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

SECTION 7: HANDLING AND STORAGE

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

STORAGE: Handle containers carefully to prevent damage and spillage.

Incompatible materials: Reducing agents, combustible materials.

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

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

OTHER PRECAUTIONS: N/A

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: N/A

VENTILATION:

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

EYE PROTECTION: Protective goggles if desired.

SKIN PROTECTION: Rubber or vinyl gloves.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

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

EXPOSURE GUIDELINES:

SECTION 8 NOTES: N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Clear, colorless, odorless liquid

PHYSICAL STATE: N/A

pH AS SUPPLIED: N/A

pH (Other): N/A

BOILING POINT: 212°F

MELTING POINT: N/A

FREEZING POINT: N/A

VAPOR PRESSURE (mmHg): 23

@ N/A

DENSITY (lb/gal): N/A

@ N/A

SPECIFIC GRAVITY (H₂O = 1): 1.1



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@ N/A

EVAPORATION RATE: >1**BASIS (=1):** N/A**SOLUBILITY IN WATER:** Complete**PERCENT SOLIDS BY WEIGHT:** N/A

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

VOLATILE ORGANIC COMPOUNDS (VOC): N/A

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

MOLECULAR WEIGHT: N/A**VISCOSITY:** N/A**SECTION 9 NOTES:**

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

SECTION 10: STABILITY AND REACTIVITY

STABLE**UNSTABLE****STABILITY:** Stable under normal conditions.**CONDITIONS TO AVOID (STABILITY):** Extreme heat and combustion.**INCOMPATIBILITY (MATERIAL TO AVOID):** Reducing agents, combustible materials.**HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:** Oxygen, which supports combustion.**HAZARDOUS POLYMERIZATION:** Will not occur.**CONDITIONS TO AVOID (POLYMERIZATION):** N/A**SECTION 10 NOTES:** N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

Acute Toxicity

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

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



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Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	1B	Causes severe skin burns and eye damage.
Serious eye damage/irritation	1	Causes serious eye damage.
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
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 <u>mykiss</u>	2.32 , Daphnia magna	0.71 (72 hr), Microcystis <u>pulverea ssp. incerta</u>

Persistence and degradability

There is no data available on the preparation itself.

Bioaccumulative potential

Not Measured

Mobility in soil

No data available.

Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

Other adverse effects

No data available.

SECTION 12 NOTES: N/A

SECTION 13: DISPOSAL CONSIDERATIONS

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



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RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

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

SECTION 14 NOTES: N/A

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS**TSCA (TOXIC SUBSTANCE CONTROL ACT):** All components of this material are either listed or exempt from listing on the TSCA**CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT):** N/A**EPCRA 301 Extremely Dangerous:** Hydrogen Peroxide**SARA 311/312 HAZARD CATEGORIES:** To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.**SARA 313 REPORTABLE INGREDIENTS:** Contains NO hazardous ingredients subject to reporting requirements of Section 313 of SARA Title II.**STATE REGULATIONS:****New Jersey RTK Substances (>1%):**

Hydrogen peroxide

Pennsylvania RTK Substances (>1%):

Hydrogen peroxide

Proposition 65 - Carcinogens (>0.0%):

No chemicals at levels which require reporting under this statute.

Proposition 65 - Developmental Toxins (>0.0%):

No chemicals at levels which require reporting under this statute.

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

No chemicals at levels which require reporting under this statute.

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



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No chemicals at levels which require reporting under this statute.

INTERNATIONAL REGULATIONS: N/A

SECTION 15 NOTES: N/A

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A

PREPARATION INFORMATION: N/A

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



SDS DATE: 9/18/2015

SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: McKesson Instrument Lubricant and Rust Inhibitor
MFR #: 53-28571

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: An oil and water emulsion for instrument lubrication and rust prevention.

2. HAZARDS IDENTIFICATION

Appearance Opaque white

Physical State Liquid

Odor Bland

Classification

This chemical does not meet the hazardous criteria set forth by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). However, this Safety Data Sheet (SDS) contains valuable information critical to the safe handling and proper use of this product. This SDS should be retained and available for employees and other users of this product.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

4. FIRST-AID MEASURES

First Aid Measures

General Advice	Provide this SDS to medical personnel for treatment. Always get medical attention when product is swallowed or when symptoms are significant or persist.
Eye Contact	Flush with water for 15 minutes. If irritation persists, call physician.
Skin Contact	Wash liberally with soap and water. If on clothes: Wash before reuse.
Inhalation	Not an expected route of exposure.
Ingestion	If patient is conscious and alert, dilute by drinking large quantities of water. Allow vomiting to occur if patient is conscious and alert, then get medical attention.

Most important symptoms and effects



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Symptoms

EYES: Possible watering, burning and redness.
 SKIN: Possible mild irritation with prolonged exposure to concentrate.
 SWALLOWED: Possible gastrointestinal irritation or disturbance.

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 Not determined.**Specific Hazards Arising from the Chemical**

This is a water based non-flammable product with no known fire or explosion hazards.

Hazardous Combustion Products Carbon oxides.**Protective equipment and precautions for firefighters**

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures**Personal Precautions**

Use personal protective equipment as required.

Methods and material for containment and cleaning up**Methods for Containment**

Prevent further leakage or spillage if safe to do so.

Methods for Clean-Up

SMALL SPILLS: Small spills (< 1 gallon) may be washed down a drain or cleaned up and disposed of into a sanitary sewer system.
 LARGE SPILLS: Large spills (> 1 gallon) should be contained and collected (by absorption or vacuuming) then disposed of properly.

7. HANDLING AND STORAGE

Precautions for safe handling**Advice on Safe Handling**

Handle in accordance with good industrial hygiene and safety practice. Do not contaminate water, food, or feed. Do not reuse empty containers. Keep containers clean & closed.

Conditions for safe storage, including any incompatibilities**Storage Conditions**

Keep out of the reach of children.

Incompatible Materials

None known based on information supplied.



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

The following information is given as general guidance

Appropriate engineering controls

Engineering Controls

Mechanical Ventilations (General): Normally sufficient
Local Exhaust: Not Normally Needed.

Individual protection measures, such as personal protective equipment

Eye/Face Protection

Avoid contact with eyes while using, wear eye protection if application might allow getting product into eyes.

Skin and Body Protection

Not normally needed, avoid prolonged contact with skin, wear gloves if unavoidable.

Respiratory Protection

Not needed. General ventilation is normally adequate.

General Hygiene Considerations Do not get into eyes. Protect food & drink from contamination by product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State
Appearance
Color

Liquid
Opaque white
Opaque white

Odor
Odor Threshold

Bland
Not determined

Property

Values

Remarks • Method

pH	9.0-10.0	
Melting Point/Freezing Point	Not established	
Boiling Point/Boiling Range	100 °C / 212 °F	
Flash Point	Not determined	
Evaporation Rate	Not established	
Flammability (Solid, Gas)	Not determined	
Upper Flammability Limits	Not available	
Lower Flammability Limit	Not available	

Vapor Pressure	Not established
Vapor Density	Not established
Specific Gravity	0.975 to 1.01
Water Solubility	Completely soluble
Solubility in other solvents	Not determined
Partition Coefficient	Not determined
Auto-ignition Temperature	Not determined
Decomposition Temperature	Not determined
Kinematic Viscosity	Not determined
Dynamic Viscosity	Not determined
Explosive Properties	Not determined
Oxidizing Properties	Not determined
Density	8.128-8.42 lbs/gal



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10. STABILITY AND REACTIVITY

Reactivity

Not reactive under normal conditions.

Chemical Stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to Avoid

Keep out of reach of children.

Incompatible Materials

None known based on information supplied.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Eye Contact

May cause mild eye irritation.

Skin Contact

May cause mild skin irritation.

Inhalation

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

Ingestion

Possible gastrointestinal irritation or disturbance.

Component Information

Information on physical, chemical and toxicological effects

Symptoms

Please see section 4 of this SDS for symptoms.

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

Carcinogenicity

This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.

Numerical measures of toxicity

Not determined

12. ECOLOGICAL INFORMATION

Ecotoxicity

The product is not expected to be hazardous to the environment.

Persistence/Degradability

Not determined



SDS DATE: 9/18/2015

Bioaccumulation

Not determined

Mobility

Not determined

Other Adverse Effects

Not determined

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods**Disposal of Wastes**

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

Contaminated Packaging

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

14. TRANSPORT INFORMATION

Note

Please see current shipping paper for most up to date shipping information, including exemptions and special circumstances.

DOT

Not regulated

IATA

Not regulated

IMDG

Not regulated

15. REGULATORY INFORMATION

International Inventories

Not determined

Legend:*TSCA - United States Toxic Substances Control Act Section 8(b) Inventory**DSL/NDL - 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*



SDS DATE: 9/18/2015

US Federal Regulations**SARA 313**

Not determined

US State Regulations**U.S. State Right-to-Know Regulations**

Not determined

16. OTHER INFORMATION

NFPA**Health Hazards****Flammability****Instability****Special Hazards Not
determined **Personal**
Protection A**

0

0

0

HMIS**Health Hazards****Flammability****Physical Hazards**

0

0

0

Issue Date

11-May-2004

Revision Date:

18-Sep-2015

Revision Note

New format

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SDS DATE: 09/01/2015***SAFETY DATA SHEET*****SECTION 1: PRODUCT AND COMPANY IDENTIFICATION****PRODUCT NAME:** McKesson Iodoform Packing Strips, 5% w/w**MFR #:** 61-59145 (1/4" x 5 yards)

61-59245 (1/2" x 5 yards)

61-59345 (1" x 5 yards)

61-59445 (2" x 5 yards)

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: N/A**SECTION 2: HAZARDS IDENTIFICATION****ROUTES OF ENTRY:** Eye contact/Skin contact/Inhalation**POTENTIAL HEALTH EFFECTS:****EYES:** Eye contact is unlikely due to physical state**SKIN:** Material may cause irritation. Liquid or vapor may be absorbed in toxicologically significant amounts. Repeated or prolonged contact may lead to dermatitis**INGESTION:** Swallowing may have the following effects: irritation of the mouth, throat and digestive tract-vomiting. A large dose may have the following effects: - damage to central nervous system- liver damage / kidney damage**INHALATION:** No adverse effects are expected**ACUTE HEALTH HAZARDS:** Not Applicable**CHRONIC HEALTH HAZARDS:** Not Applicable**MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE:** No data**CARCINOGENICITY****OSHA:** N/A**ACGIH:** N/A**NTP:** N/A**IARC:** N/A**OTHER:** N/A**SECTION 2 NOTES:** N/A**SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS**

INGREDIENT	CAS NO.	%	Exposure Limits
Iodoform	75-47-8	5	No Data
Polyethylene Glycol	25322-68-3	No data	No data
Methylcellulose	9004-67-5	No data	No data
Water	7732-18-5	No data	No data

SECTION 3 NOTES: N/A

SDS DATE: 09/01/2015

SECTION 4: FIRST-AID MEASURES

EYES: In case of contact, immediately flood the eye with plenty of water for at least 15 minutes, holding the eye open. Obtain medical attention if soreness or redness persists.

SKIN: If skin irritation develops, or other symptoms occur, discontinue use. Seek medical attention if symptoms persist.

INGESTION: Do not induce vomiting. Have victim drink 1-3 glasses of water to dilute stomach contents. Never administer anything by mouth if a victim is losing consciousness, is unconscious or is convulsing. Obtain medical attention immediately.

INHALATION If there is difficulty in breathing, give oxygen. Seek medical attention if symptoms persist

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: Treat symptomatically

SECTION 4 NOTES: N/A

SECTION 5: FIRE-FIGHTING MEASURES

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

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

AUTOIGNITION TEMPERATURE: 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: Non Flammable. Select extinguishing agent appropriate to other materials involved.

SPECIAL FIRE FIGHTING PROCEDURES: Wear full protective clothing and self-contained breathing apparatus

UNUSUAL FIRE AND EXPLOSION HAZARDS: This product may give rise to hazardous fumes in a fire.

HAZARDOUS DECOMPOSITION PRODUCTS: Not applicable

SECTION 5 NOTES: N/A

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: No Specific measures necessary

SECTION 6 NOTES: N/A

SECTION 7: HANDLING AND STORAGE

HANDLING: Must generally be handled using gloves or specially cleaned equipment in order to keep it sterile

STORAGE: Keep container tightly closed when not in use. Storage area should be cool, dry and well ventilated

OTHER PRECAUTIONS: N/A

SECTION 7 NOTES: N/A

SDS DATE: 09/01/2015

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:**VENTILATION:** No data**RESPIRATORY PROTECTION:** Not normally required under normal conditions**EYE PROTECTION:** Eye protection not normally required. However, care should be taken to avoid accidental exposure.**SKIN PROTECTION:** Skin protection not normally required. Product is designed to be in contact with skin**OTHER PROTECTIVE CLOTHING OR EQUIPMENT:** N/A**WORK HYGIENIC PRACTICES:** N/A**EXPOSURE GUIDELINES:** N/A**SECTION 8 NOTES:** N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Opaque-Light Yellow, Iodine**PHYSICAL STATE:** Cotton cloth saturated with liquid**pH AS SUPPLIED:** No Data**pH (Other):** N/A**BOILING POINT:** No Data**MELTING POINT:** N/A**FREEZING POINT:** N/A**VAPOR PRESSURE (mmHg):** N/A

@ N/A

DENSITY (lb/gal): N/A

@ N/A

SPECIFIC GRAVITY (H₂O = 1): N/A

@ N/A

EVAPORATION RATE: N/A**BASIS (=1):** N/A**SOLUBILITY IN WATER:** No Data**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:** N/A



SDS DATE: 09/01/2015

SECTION 10: STABILITY AND REACTIVITY

STABLE**UNSTABLE**

STABILITY: Stable under normal conditions

CONDITIONS TO AVOID (STABILITY): Heat-High Temperatures-Pressure

INCOMPATIBILITY (MATERIAL TO AVOID): Acids- Bases-Oxidizing agents

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: Oxides of carbon – Hydriodic acid

HAZARDOUS POLYMERIZATION: Will not occur

CONDITIONS TO AVOID (POLYMERIZATION): N/A

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: N/A**SECTION 11 NOTES:** N/A

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: N/A**SECTION 12 NOTES:** N/A

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Disposal of in accordance with all applicable local and national regulations. Dispose of containers with care.**RCRA HAZARD CLASS:** N/A**SECTION 13 NOTES:** N/A

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION

PROPER SHIPPING NAME: N/A

HAZARD CLASS: N/A

DOT SHIPPING ID NUMBER: N/A

DOT PACKING GROUP: N/A

DOT 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

SDS DATE: 09/01/2015

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TSCA (TOXIC SUBSTANCE CONTROL ACT): N/A

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

SARA 311/312 HAZARD CATEGORIES: N/A

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

STATE REGULATIONS: N/A

INTERNATIONAL REGULATIONS: N/A

SECTION 15 NOTES: N/A

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A

PREPARATION INFORMATION: N/A

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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.



SDS DATE: 8/7/2015

**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

<u>INGREDIENT</u>	<u>CAS NO.</u>	<u>%</u>	<u>Exposure Limits</u>
Isopropyl Alcohol	67-63-0	50-75	OSHA TWA 400 ppm (980mg/m ³) STEL 500 ppm ACGIH TWA: 200 ppm STEL: 400 ppm Revised 2003, NIOSH TWA 400 ppm (980 mg/m ³) ST 500 ppm (1225 mg/m ³)

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.



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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



HEALTH: N/A

FLAMMABILITY: N/A

REACTIVITY: N/A

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PERSONAL: N/A**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:



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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 soiled clothing 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 heat, sparks and open flame.



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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.



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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

Exemption 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

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SDS DATE: 11/12/15

SAFETY DATA SHEET**SECTION 1: PRODUCT AND COMPANY IDENTIFICATION****PRODUCT NAME:** McKesson Lubricating Jelly**MFR #:** 119-8919, 119-8942, 119-8946

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: Personal/Professional (clinical) lubricant**SECTION 2: HAZARDS IDENTIFICATION****ROUTES OF ENTRY:** N/A

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE: The product does not need classification according to OSHA HazCom Standard 29 CFR paragraph (d) of §1910.1200(g) and GHS Rev 03.

POTENTIAL HEALTH EFFECTS:**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:** N/A**ACGIH:** N/A**NTP:** N/A**IARC:** N/A**OTHER:** N/A**SECTION 2 NOTES:** N/A**SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS****CHEMICAL CHARACTERIZATION:** Mixtures**DESCRIPTION:** Mixture of substances listed below with nonhazardous additions.

INGREDIENT	CAS NO.	%	Exposure Limits
Water, distilled, conductivity or of similar purity	7732-18-5 (RTECS: ZC 0110000)	60-90%	N/A
Propylene Glycol	57-55-6 (RTECS: TY 2000000)	5-10%	N/A
Hydroxypropyl Methylcellulose, Combustible dust	9004-65-3	≤2.5%	N/A

SECTION 3 NOTES: N/A



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SECTION 4: FIRST-AID MEASURES

EYES: Flush eyes with plenty of 1% physiological saline solution. If no saline is available, flush with copious amounts of water.

SKIN: Generally the product does not irritate the skin.

INGESTION: If swallowed and symptoms occur, consult a doctor.

INHALATION: Not a normal route of entry.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: N/A

SECTION 4 NOTES: N/A

SECTION 5: FIRE-FIGHTING MEASURES

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

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

AUTOIGNITION TEMPERATURE: N/A

NFPA HAZARD CLASSIFICATION

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

HMS HAZARD CLASSIFICATION

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

EXTINGUISHING MEDIA: CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam

SPECIAL FIRE FIGHTING PROCEDURES: If involved in a fire, the packaging materials may produce poisonous gas.

UNUSUAL FIRE AND EXPLOSION HAZARDS: N/A

HAZARDOUS DECOMPOSITION PRODUCTS: N/A

SECTION 5 NOTES: As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES:

Personal precautions, protective equipment and emergency procedures Product is slippery when spilled.

Environmental precautions: No special measures required.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (i.e. sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to section 13.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 6 NOTES: N/A

SECTION 7: HANDLING AND STORAGE

HANDLING: No special measures required.



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STORAGE: No special measures required.**OTHER PRECAUTIONS:** N/A**SECTION 7 NOTES:** N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: No further data; see section 7.**VENTILATION:** N/A**RESPIRATORY PROTECTION:** N/A**EYE PROTECTION:** Goggles recommended during refilling.**SKIN PROTECTION:** N/A**OTHER PROTECTIVE CLOTHING OR EQUIPMENT:** N/A**WORK HYGIENIC PRACTICES:** The usual precautionary measures for handling chemicals should be followed.**EXPOSURE GUIDELINES:**

Components with occupational exposure limits:

57-55-6 Propylene Glycol

WEEL Long-term value: 10 mg/ m³**SECTION 8 NOTES:** N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Translucent, Odorless**PHYSICAL STATE:** Gel**pH AS SUPPLIED:** 5.6 – 6.7**pH (Other):** N/A**BOILING POINT:** °F**MELTING POINT:** N/A**FREEZING POINT:** N/A**VAPOR PRESSURE (mmHg):** N/A

@ N/A

DENSITY (20DegC, 68DegF): 1.01 g/cm³ (8.428lbs/gal)

@ N/A

SPECIFIC GRAVITY (H₂O = 1): N/A

@ N/A

EVAPORATION RATE: N/A**BASIS (=1):** N/A**SOLUBILITY IN WATER:** Soluble**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



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VISCOSITY: N/A

SECTION 9 NOTES: N/A

SECTION 10: STABILITY AND REACTIVITY

STABLEUNSTABLE**STABILITY:** Stable under normal conditions**CONDITIONS TO AVOID (STABILITY):** If involved in a fire, the packaging materials may produce poisonous gas.**INCOMPATIBILITY (MATERIAL TO AVOID):****HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:****HAZARDOUS POLYMERIZATION:** N/A**CONDITIONS TO AVOID (POLYMERIZATION):** N/A

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:**ACUTE TOXICITY:**

LD/LC50 values that are relevant for classification:

57-55-6	Propylene Glycol	
Oral	LD50	20000 mg/kg (rat)
Oral	LD50	20800 mg/kg (rabbit)
Inhalative	LC50/96 hours	52930 mg/l (Pimephales)
	Intravenous	6630 mg/kg (mouse)
		6423 mg/kg (rat)
		6500 mg/kg (rabbit)

SECTION 11 NOTES: The product is not subject to classification according to internally approved calculation methods for preparations: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:

AQUATIC TOXICITY: 57-55-6 Propylene Glycol
EC500 >1000 mg/l (daphnia)

PERSISTENCE AND DEGRADABILITY: No further relevant information available.**BIOACCUMULATIVE POTENTIAL:** No further relevant information available.**MOBILITY IN SOIL:** No further relevant information available.**GENERAL NOTES:** Not known to be hazardous to water.**RESULTS AND PBT AND vPvB ASSESSMENT:****PBT:** Not applicable.**vPvB:** Not applicable.**OTHER ADVERSE EFFECTS:** No further relevant information available.

SECTION 12 NOTES: N/A

SECTION 13: DISPOSAL CONSIDERATIONS



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WASTE DISPOSAL METHOD: Recommendation: Small quantities can be disposed of with household waste.

UNCLEANED PACKAGINGS: Recommendation: Disposal must be made according to official regulations.

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION

PROPER SHIPPING NAME: N/A

HAZARD CLASS: N/A

DOT SHIPPING ID NUMBER: N/A

DOT PACKING GROUP: N/A

DOT 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: ADR: Regulated

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS: The product is subject to be classified according with the latest version of the regulations on hazardous substances.

TSCA (TOXIC SUBSTANCE CONTROL ACT): N/A

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

SARA 311/312 HAZARD CATEGORIES: N/A

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

STATE REGULATIONS: N/A

INTERNATIONAL REGULATIONS: N/A

SECTION 15 NOTES: N/A

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose. A Chemical Safety Assessment has not been carried out.

PREPARATION INFORMATION: N/A



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WASTE DISPOSAL METHOD: Recommendation: Small quantities can be disposed of with household waste.

ABBREVIATIONS AND ACRONYMS:

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road



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ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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



SDS DATE: 9/18/2015

SAFETY DATA SHEET**SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**

PRODUCT NAME: McKesson Multi-Enzymatic Cleanser Fresh Mint Fragrance
MFR #: 53-28501

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

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

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

PRODUCT DESCRIPTION: A surfactant and multi-enzyme formulation for instrument cleaning.

2. HAZARDS IDENTIFICATION

Appearance Clear turquoise liquid

Physical State Liquid

Odor Spearmint/Eucalyptus

Classification

Serious eye damage/eye irritation

Category 2

Signal Word

Warning

Hazard Statements

Causes serious eye irritation

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling

Wear eye/face protection

Precautionary Statements - Response

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
 Get medical attention if irritation occurs

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%
Isopropyl alcohol	67-63-0	<5
Monoethanolamine	141-43-5	<2
Propylene Glycol	57-55-6	<5

4. FIRST-AID MEASURES



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First Aid Measures

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention if irritation occurs.
Skin Contact	Wash hands thoroughly after handling.
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call Poison Control or doctor/physician.
Ingestion	Dilute by giving a large amount of water. Allow vomiting to occur, then get medical attention.

Most important symptoms and effects

Symptoms	Eye contact may cause redness or burning sensation. Prolonged or repeated skin contact may cause irritation. May cause gastrointestinal disturbance.

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 Not determined.

Specific Hazards Arising from the Chemical

Non-flammable.

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	Use personal protective equipment as required.
Environmental Precautions	See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for Clean-Up	Small spills (less than 1 gallon) may be washed down a drain with lots of water or cleaned up and disposed of into a sanitary sewer system. Large spills (more than 1 gallon) should be contained and collected (by absorption [sand, clay, or other absorbent material] or vacuuming) then disposed of properly.

7. HANDLING AND STORAGE



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Precautions for safe handling**Advice on Safe Handling**

Wash thoroughly after handling. Use personal protection recommended in Section 8. Avoid breathing vapors or mists.

Conditions for safe storage, including any incompatibilities**Storage Conditions**

Keep containers tightly closed in a dry, cool and well-ventilated place. Do not contaminate food or feed stuffs. Do not reuse container. Keep out of the reach of children.

Incompatible Materials

None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Isopropyl alcohol 67-63-0	STEL: 400 ppm TWA: 200 ppm	TWA: 400 ppm TWA: 980 mg/m ³ (vacated) TWA: 400 ppm (vacated) TWA: 980 mg/m ³ (vacated) STEL: 500 ppm (vacated) STEL: 1225 mg/m ³	IDLH: 2000 ppm TWA: 400 ppm TWA: 980 mg/m ³ STEL: 500 ppm STEL: 1225 mg/m ³
Propylene Glycol 57-55-6	TWA: 10mg/m ³	TWA: 10mg/m ³	-
Monoethanolamine 141-43-5	STEL: 6 ppm TWA: 3 ppm	TWA: 3 ppm TWA: 6 mg/m ³ (vacated) TWA: 3 ppm (vacated) TWA: 8 mg/m ³ (vacated) STEL: 6 ppm (vacated) STEL: 15 mg/m ³	IDLH: 30 ppm TWA: 3 ppm TWA: 8 mg/m ³ STEL: 6 ppm STEL: 15 mg/m ³

Appropriate engineering controls**Engineering Controls**

Ventilation systems.

Individual protection measures, such as personal protective equipment**Eye/Face Protection**

Risk of contact: Wear approved safety goggles.

Skin and Body Protection

For prolonged or repeated skin contact use suitable protective gloves.

Respiratory Protection

No protection is ordinarily required under normal conditions of use and with adequate ventilation.

General Hygiene Considerations Do not get in eyes. Keep away from food and drink.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State
Appearance
Color

Liquid
 Clear turquoise liquid
 Turquoise

Odor
Odor Threshold

Spearmint/Eucalyptus
 Not determined

Property**Values****Remarks • Method****pH**

7.5-8.5 (concentrate)

Melting Point/Freezing Point

Not established



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Boiling Point/Boiling Range	100 °C / 212 °F
Flash Point	Not flammable
Evaporation Rate	Not established
Flammability (Solid, Gas)	n/a-liquid
Upper Flammability Limits	Not available
Lower Flammability Limit	Not available
Vapor Pressure	Not established
Vapor Density	Not established
Specific Gravity	1.00-1.04
Water Solubility	Completely soluble
Solubility in other solvents	Not determined
Partition Coefficient	Not determined
Autoignition Temperature	Not determined
Decomposition Temperature	Not determined
Kinematic Viscosity	Not determined
Property	Values
Dynamic Viscosity	Not determined
Explosive Properties	Not determined
Oxidizing Properties	Not determined

Remarks • Method

10. STABILITY AND REACTIVITY

Reactivity

Not reactive under normal conditions.

Chemical Stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to Avoid

Keep out of reach of children.

Incompatible Materials

None known.

Hazardous Decomposition Products

None known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Eye Contact

Causes serious eye irritation.

Skin Contact

Avoid contact with skin.

Inhalation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Ingestion

Do not taste or swallow.



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Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Isopropyl alcohol 67-63-0	= 4396 mg/kg (Rat)	= 12800 mg/kg (Rat) = 12870 mg/kg (Rabbit)	= 72.6 mg/L (Rat) 4 h
Propylene Glycol 57-55-6	= 20000 mg/kg (Rat)	= 20800 mg/kg (Rabbit)	-
Monoethanolamine 141-43-5	= 1720 mg/kg (Rat)	= 1 mL/kg (Rabbit) = 1025 mg/kg (Rabbit)	-

Information on physical, chemical and toxicological effects**Symptoms**

Please see section 4 of this SDS for symptoms.

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

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Carcinogenicity

Isopropyl Alcohol (IPA) is listed as an IARC Monograph Group 3 chemical. However, IARC Group 3 chemicals are "not classifiable as human carcinogens".

Chemical Name	ACGIH	IARC	NTP	OSHA
Isopropyl alcohol 67-63-0		Group 3		X

Legend*IARC (International Agency for Research on Cancer)**Group 3 IARC components are "not classifiable as human carcinogens"**OSHA (Occupational Safety and Health Administration of the US Department of Labor)**X - Present***Numerical measures of toxicity**

Not determined

12. ECOLOGICAL INFORMATION

Ecotoxicity

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Isopropyl alcohol 67-63-0	1000: 96 h Desmodesmus subspicatus mg/L EC50 1000: 72 h Desmodesmus subspicatus mg/L EC50	9640: 96 h Pimephales promelas mg/L LC50 flow-through 11130: 96 h Pimephales promelas mg/L LC50 static 1400000: 96 h Lepomis macrochirus µg/L LC50		13299: 48 h Daphnia magna mg/L EC50
Propylene Glycol 57-55-6	19000: 96 h Pseudokirchneriella subcapitata mg/L EC50	51600: 96 h Oncorhynchus mykiss mg/L LC50 static 41 - 47: 96 h Oncorhynchus mykiss mL/L LC50 static 51400: 96 h Pimephales promelas mg/L LC50 static 710: 96 h Pimephales promelas mg/L LC50		10000: 24 h Daphnia magna mg/L EC50 1000: 48 h Daphnia magna mg/L EC50 Static



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Monoethanolamine 141-43-5	15: 72 h Desmodium subspicatus mg/L EC50	227: 96 h Pimephales promelas mg/L LC50 flow- through 3684: 96 h Brachydanio rerio mg/L LC50 static 300 - 1000: 96 h Lepomis macrochirus mg/L LC50 static 114 - 196: 96 h Oncorhynchus mykiss mg/L LC50 static 200: 96 h Oncorhynchus mykiss mg/L LC50 flow-through		65: 48 h Daphnia magna mg/L EC50

Persistence/Degradability

Not determined

Bioaccumulation

Not determined

Mobility

Chemical Name	Partition Coefficient
Isopropyl alcohol 67-63-0	0.05
Monoethanolamine 141-43-5	-1.91

Other Adverse Effects

Not determined

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods**Disposal of Wastes**

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

Contaminated Packaging

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

California Hazardous Waste Status

Chemical Name	California Hazardous Waste Status
Isopropyl alcohol 67-63-0	Toxic Ignitable

14. TRANSPORT INFORMATION

Note

Please see current shipping paper for most up to date shipping information, including exemptions and special circumstances.

DOT

Not regulated

IATA

Not regulated



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IMDG

Not regulated

15. REGULATORY INFORMATION

International Inventories

Not determined

US Federal RegulationsSARA 313

Chemical Name	CAS No	Weight-%	SARA 313 - Threshold Values %
Isopropyl alcohol - 67-63-0	67-63-0	<5	1.0

US State RegulationsU.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Isopropyl alcohol 67-63-0	X	X	X
Propylene Glycol 57-55-6	X		X
Monoethanolamine 141-43-5	X	X	X

16. OTHER INFORMATION

NFPA**Health Hazards**

Not determined

Flammability

Not determined

Instability

Not determined

Special Hazards

Not determined

HMIS**Health Hazards**

0

Flammability

0

Physical Hazards

0

Personal Protection

0

Issue Date

09-Mar-2012

Revision Date:

18-Sep-2015

Revision Note

Format Update

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SDS DATE: 9/18/2015

SAFETY DATA SHEET**SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**

PRODUCT NAME: McKesson Multi-Enzymatic Cleanser Spring Fragrance
MFR #: 53-28502

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

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

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

PRODUCT DESCRIPTION: A surfactant and multi-enzyme formulation for instrument cleaning.

2. HAZARDS IDENTIFICATION

Appearance Clear turquoise liquid

Physical State Liquid

Odor Spearmint/Eucalyptus

Classification

Serious eye damage/eye irritation

Category 2

Signal Word

Warning

Hazard Statements

Causes serious eye irritation

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling

Wear eye/face protection

Precautionary Statements - Response

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
 Get medical attention if irritation occurs

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%
Isopropyl alcohol	67-63-0	<5
Monoethanolamine	141-43-5	<2
Propylene Glycol	57-55-6	<5

4. FIRST-AID MEASURES



SDS DATE: 9/18/2015

First Aid Measures

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention if irritation occurs.
Skin Contact	Wash hands thoroughly after handling.
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call Poison Control or doctor/physician.
Ingestion	Dilute by giving a large amount of water. Allow vomiting to occur, then get medical attention.

Most important symptoms and effects

Symptoms	Eye contact may cause redness or burning sensation. Prolonged or repeated skin contact may cause irritation. May cause gastrointestinal disturbance.

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 Not determined.

Specific Hazards Arising from the Chemical

Non-flammable.

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	Use personal protective equipment as required.
Environmental Precautions	See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for Clean-Up	Small spills (less than 1 gallon) may be washed down a drain with lots of water or cleaned up and disposed of into a sanitary sewer system. Large spills (more than 1 gallon) should be contained and collected (by absorption [sand, clay, or other absorbent material] or vacuuming) then disposed of properly.

7. HANDLING AND STORAGE



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Precautions for safe handling**Advice on Safe Handling**

Wash thoroughly after handling. Use personal protection recommended in Section 8. Avoid breathing vapors or mists.

Conditions for safe storage, including any incompatibilities**Storage Conditions**

Keep containers tightly closed in a dry, cool and well-ventilated place. Do not contaminate food or feed stuffs. Do not reuse container. Keep out of the reach of children.

Incompatible Materials

None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Isopropyl alcohol 67-63-0	STEL: 400 ppm TWA: 200 ppm	TWA: 400 ppm TWA: 980 mg/m ³ (vacated) TWA: 400 ppm (vacated) TWA: 980 mg/m ³ (vacated) STEL: 500 ppm (vacated) STEL: 1225 mg/m ³	IDLH: 2000 ppm TWA: 400 ppm TWA: 980 mg/m ³ STEL: 500 ppm STEL: 1225 mg/m ³
Propylene Glycol 57-55-6	TWA: 10mg/m ³	TWA: 10mg/m ³	-
Monoethanolamine 141-43-5	STEL: 6 ppm TWA: 3 ppm	TWA: 3 ppm TWA: 6 mg/m ³ (vacated) TWA: 3 ppm (vacated) TWA: 8 mg/m ³ (vacated) STEL: 6 ppm (vacated) STEL: 15 mg/m ³	IDLH: 30 ppm TWA: 3 ppm TWA: 8 mg/m ³ STEL: 6 ppm STEL: 15 mg/m ³

Appropriate engineering controls**Engineering Controls**

Ventilation systems.

Individual protection measures, such as personal protective equipment**Eye/Face Protection**

Risk of contact: Wear approved safety goggles.

Skin and Body Protection

For prolonged or repeated skin contact use suitable protective gloves.

Respiratory Protection

No protection is ordinarily required under normal conditions of use and with adequate ventilation.

General Hygiene Considerations Do not get in eyes. Keep away from food and drink.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State
Appearance
Color

Liquid
Clear turquoise liquid
Turquoise

Odor
Odor Threshold

Spearmint/Eucalyptus
Not determined

Property**Values****Remarks • Method**

pH

7.5-8.5 (concentrate)

Melting Point/Freezing Point

Not established



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Boiling Point/Boiling Range	100 °C / 212 °F
Flash Point	Not flammable
Evaporation Rate	Not established
Flammability (Solid, Gas)	n/a-liquid
Upper Flammability Limits	Not available
Lower Flammability Limit	Not available
Vapor Pressure	Not established
Vapor Density	Not established
Specific Gravity	1.00-1.04
Water Solubility	Completely soluble
Solubility in other solvents	Not determined
Partition Coefficient	Not determined
Autoignition Temperature	Not determined
Decomposition Temperature	Not determined
Kinematic Viscosity	Not determined
Property	Values
Dynamic Viscosity	Not determined
Explosive Properties	Not determined
Oxidizing Properties	Not determined

Remarks • Method

10. STABILITY AND REACTIVITY

Reactivity

Not reactive under normal conditions.

Chemical Stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to Avoid

Keep out of reach of children.

Incompatible Materials

None known.

Hazardous Decomposition Products

None known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Eye Contact

Causes serious eye irritation.

Skin Contact

Avoid contact with skin.

Inhalation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Ingestion

Do not taste or swallow.



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Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Isopropyl alcohol 67-63-0	= 4396 mg/kg (Rat)	= 12800 mg/kg (Rat) = 12870 mg/kg (Rabbit)	= 72.6 mg/L (Rat) 4 h
Propylene Glycol 57-55-6	= 20000 mg/kg (Rat)	= 20800 mg/kg (Rabbit)	-
Monoethanolamine 141-43-5	= 1720 mg/kg (Rat)	= 1 mL/kg (Rabbit) = 1025 mg/kg (Rabbit)	-

Information on physical, chemical and toxicological effects**Symptoms**

Please see section 4 of this SDS for symptoms.

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

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Carcinogenicity

Isopropyl Alcohol (IPA) is listed as an IARC Monograph Group 3 chemical. However, IARC Group 3 chemicals are "not classifiable as human carcinogens".

Chemical Name	ACGIH	IARC	NTP	OSHA
Isopropyl alcohol 67-63-0		Group 3		X

Legend*IARC (International Agency for Research on Cancer)**Group 3 IARC components are "not classifiable as human carcinogens"**OSHA (Occupational Safety and Health Administration of the US Department of Labor)**X - Present***Numerical measures of toxicity**

Not determined

12. ECOLOGICAL INFORMATION

Ecotoxicity

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Isopropyl alcohol 67-63-0	1000: 96 h Desmodesmus subspicatus mg/L EC50 1000: 72 h Desmodesmus subspicatus mg/L EC50	9640: 96 h Pimephales promelas mg/L LC50 flow-through 11130: 96 h Pimephales promelas mg/L LC50 static 1400000: 96 h Lepomis macrochirus µg/L LC50		13299: 48 h Daphnia magna mg/L EC50
Propylene Glycol 57-55-6	19000: 96 h Pseudokirchneriella subcapitata mg/L EC50	51600: 96 h Oncorhynchus mykiss mg/L LC50 static 41 - 47: 96 h Oncorhynchus mykiss mL/L LC50 static 51400: 96 h Pimephales promelas mg/L LC50 static 710: 96 h Pimephales promelas mg/L LC50		10000: 24 h Daphnia magna mg/L EC50 1000: 48 h Daphnia magna mg/L EC50 Static



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Monoethanolamine 141-43-5	15: 72 h Desmodium subspicatus mg/L EC50	227: 96 h Pimephales promelas mg/L LC50 flow- through 3684: 96 h Brachydanio rerio mg/L LC50 static 300 - 1000: 96 h Lepomis macrochirus mg/L LC50 static 114 - 196: 96 h Oncorhynchus mykiss mg/L LC50 static 200: 96 h Oncorhynchus mykiss mg/L LC50 flow-through		65: 48 h Daphnia magna mg/L EC50

Persistence/Degradability

Not determined

Bioaccumulation

Not determined

Mobility

Chemical Name	Partition Coefficient
Isopropyl alcohol 67-63-0	0.05
Monoethanolamine 141-43-5	-1.91

Other Adverse Effects

Not determined

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods**Disposal of Wastes**

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

Contaminated Packaging

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

California Hazardous Waste Status

Chemical Name	California Hazardous Waste Status
Isopropyl alcohol 67-63-0	Toxic Ignitable

14. TRANSPORT INFORMATION

Note

Please see current shipping paper for most up to date shipping information, including exemptions and special circumstances.

DOT

Not regulated

IATA

Not regulated



SDS DATE: 9/18/2015

IMDG

Not regulated

15. REGULATORY INFORMATION

International Inventories

Not determined

US Federal RegulationsSARA 313

Chemical Name	CAS No	Weight-%	SARA 313 - Threshold Values %
Isopropyl alcohol - 67-63-0	67-63-0	<5	1.0

US State RegulationsU.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Isopropyl alcohol 67-63-0	X	X	X
Propylene Glycol 57-55-6	X		X
Monoethanolamine 141-43-5	X	X	X

16. OTHER INFORMATION

NFPA**Health Hazards**

Not determined

Flammability

Not determined

Instability

Not determined

Special Hazards

Not determined

HMIS**Health Hazards**

0

Flammability

0

Physical Hazards

0

Personal Protection

0

Issue Date

09-Mar-2012

Revision Date:

18-Sep-2015

Revision Note

Format Update

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

McKESSON

SDS DATE: 03/01/2016

SAFETY DATA SHEET**SECTION 1: PRODUCT AND COMPANY IDENTIFICATION****PRODUCT NAME:** McKesson Oil Emulsion Dressing**MFR #:** 61-77041 (3" x 3")
61-77042 (3"x 8")**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:** N/A**SECTION 2: HAZARDS IDENTIFICATION****ROUTES OF ENTRY:** Eye contact/ Ingestion/ Skin**POTENTIAL HEALTH EFFECTS:****EYES:** Eye contact may cause slight irritation**SKIN:** This product may be irritating to the skin and skin absorption is not associated with any health effects.**INGESTION:** A large dose may have the following effects: nausea, vomiting, diarrhea, abdominal pain, and intestinal obstruction.**INHALATION:** No adverse effects are expected during normal conditions of use.**ACUTE HEALTH HAZARDS:** Not Applicable**CHRONIC HEALTH HAZARDS:** Not Applicable**MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE:** No data**CARCINOGENICITY****OSHA:** N/A**ACGIH:** N/A**NTP:** N/A**IARC:** N/A**OTHER:** N/A**SECTION 2 NOTES:** N/A**SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS**

INGREDIENT	CAS NO.	Od	Exposure Limits
Petrolatum White	8009-03-8	No data	No data
Mineral Oil	8012-95-1	No data	No data
Arlacel C	1338-41-6	No data	No data
RODI water	NA	No data	No data
Gauze acetate	NA	No data	No data

SECTION 3 NOTES: N/A**SECTION 4: FIRST-AID MEASURES****EYES:** In case of contact, immediately flood the eye with plenty of water for at least 15 minutes, holding the eye open. Obtain medical attention if soreness or redness persists.

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SKIN: If skin irritation develops, or other symptoms occur, discontinue use. Seek medical attention if symptoms persist.

INGESTION: Do not induce vomiting. Have victim drink 1-3 glasses of water to dilute stomach contents. Never administer anything by mouth if a victim is losing consciousness, is unconscious or is convulsing. Obtain medical attention immediately.

INHALATION If there is difficulty in breathing, give oxygen. Seek medical attention if symptoms persist

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: Treats symptomatically

SECTION 4 NOTES: N/A

SECTION 5: FIRE-FIGHTING MEASURES

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

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

AUTOIGNITION TEMPERATURE: 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: Non Flammable. Select extinguishing agent appropriate to other materials involved

SPECIAL FIRE FIGHTING PROCEDURES: Wear full protective clothing and self contained breathing apparatus

UNUSUAL FIRE AND EXPLOSION HAZARDS: None known

HAZARDOUS DECOMPOSITION PRODUCTS: Not applicable

SECTION 5 NOTES: N/A

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: No Specific measures necessary

SECTION 6 NOTES: N/A

SECTION 7: HANDLING AND STORAGE

HANDLING: No specific measures

STORAGE: Keep container tightly closed when not in use. Storage area should be cool, dry and well ventilated.

OTHER PRECAUTIONS: N/A

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

VENTILATION: Not normally needed

RESPIRATORY PROTECTION: Not normally required

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EYE PROTECTION: Eye protection not normally required. However, care should be taken to avoid accidental exposure.

SKIN PROTECTION: Normal work wear

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

WORK HYGIENIC PRACTICES: N/A

EXPOSURE GUIDELINES: N/A

SECTION 8 NOTES: N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: White-Off white PHYSICAL

STATE: Gauze saturated with oil emulsion pH AS

SUPPLIED: No data

pH (Other): N/A

BOILING POINT: No Data

MELTING POINT: N/A

FREEZING POINT: N/A

VAPOR PRESSURE (mmHg): N/A

@ N/A

DENSITY (lb/gal): N/A

@ N/A

SPECIFIC GRAVITY (H₂O = 1): N/A

@ N/A

EVAPORATION RATE: N/A

BASIS (=1): N/A

SOLUBILITY IN WATER: No data

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: N/A

SECTION 10: STABILITY AND REACTIVITY

STABLE

UNSTABLE

STABILITY: Stable under normal conditions

CONDITIONS TO AVOID (STABILITY): Heat, High Temperatures, Pressure

INCOMPATIBILITY (MATERIAL TO AVOID): Oxidizing agents

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: None

McKESSON

SDS DATE: 03/01/2016

HAZARDOUS POLYMERIZATION: Will not occur

CONDITIONS TO AVOID (POLYMERIZATION): N/A

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: N/A

SECTION 11 NOTES: N/A

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: N/A

SECTION 12 NOTES: N/A

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose by landfill or can be incinerated, in accordance with all applicable local and national regulations.

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION

PROPER SHIPPING NAME: N/A

HAZARD CLASS: N/A

DOT SHIPPING 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): N/A

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

SARA 311/312 HAZARD CATEGORIES: N/A

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

McKESSON

SDS DATE: 03/01/2016

STATE REGULATIONS: N/A

INTERNATIONAL REGULATIONS: N/A

SECTION 15 NOTES: N/A

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A

PREPARATION INFORMATION: N/A

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SAFETY DATA SHEET

McKESSON

SDS11.19.2015

1. Identification**PRODUCT NAME:** McKesson Skin Marker Ink – Violet (19-0751, 19-0752, 19-0771, 19-0772), Select Skin Marker Ink – Violet (6007, 6008, 6009, 6010)**MFR #:** 19-0751, 19-0752, 19-0771, 19-0772, 6007, 6008, 6009, 6010**RECOMMENDED USE:** Used for surgical marking on intact skin.**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: N/A

2. Hazard(s) identification

Physical hazards	Flammable Liquids	Category 3
Health Hazards	Serious eye damage/eye irritation	Category 1
	Carcinogenicity	Category 2
	Specific Target Organ Toxicity, Single Exposure	Category 3 narcotic effects
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 2
	Hazardous to the aquatic environment, long-term hazard	Category 2
OSHA defined hazards	Not classified.	

Label elements**Signal word** Danger**Hazard statement** Flammable liquid and vapor. Causes serious eye damage. May cause drowsiness or dizziness. Suspected of causing cancer. Toxic to aquatic life with long lasting effects.**Precautionary statement****Prevention**

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Avoid breathing mist or vapor. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.

Response

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. In case of fire: Use appropriate media to extinguish. Collect spillage.

Storage

Store in a well-ventilated place. Keep container tightly closed. Keep cool. Store locked up.

Disposal

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

Hazard(s) not otherwise classified (HNOC)

None known.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
TRADE SECRET DYE	Proprietary	Proprietary
TRADE SECRET SOLVENT	Proprietary	Proprietary

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

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
Skin contact	Take off immediately all contaminated clothing. Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	May cause drowsiness and dizziness. Headache. Nausea, vomiting. Irritation of nose and throat. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Thermal burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital. Keep victim under observation. Symptoms may be delayed.
General information	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Alcohol resistant foam. Water fog. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	Vapors may form explosive mixtures with air. Vapors may travel considerable distance to a source of ignition and flash back. During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Flammable liquid and vapor.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Keep combustibles (wood, paper, oil, etc.) away from spilled material. This material is classified as a water pollutant under the Clean Water Act and should be prevented from contaminating soil or from entering sewage and drainage systems which lead to waterways.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water.

Small Spills: Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

7. Handling and storage**Precautions for safe handling**

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. When using do not smoke. Explosion-proof general and local exhaust ventilation. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Use non-sparking tools and explosion-proof equipment. Do not get this material in contact with eyes. Avoid breathing mist or vapor. Avoid prolonged exposure. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store locked up. Keep away from heat, sparks and open flame. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Store in a cool, dry place out of direct sunlight. Store in original tightly closed container. Store in a well-ventilated place. Keep in an area equipped with sprinklers. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection**Occupational exposure limits****US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**

Components	Type	Value
TRADE SECRET SOLVENT (CAS Proprietary)	PEL	980 mg/m ³
		400 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
TRADE SECRET SOLVENT (CAS Proprietary)	STEL	400 ppm
	TWA	200 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
TRADE SECRET SOLVENT (CAS Proprietary)	STEL	1225 mg/m ³
	TWA	500 ppm
		980 mg/m ³
		400 ppm

Biological limit values**ACGIH Biological Exposure Indices**

Components	Value	Determinant	Specimen	Sampling Time
TRADE SECRET SOLVENT (CAS Proprietary)	40 mg/l	Acetone	Urine	*

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

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas. Provide easy access to water supply and eye wash facilities.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other Wear suitable protective clothing. Use of an impervious apron is recommended.

Respiratory protection No specific recommendations due to the small quantities handled. Respiratory protection must be used if air contamination exceeds acceptable level. Chemical respirator with organic vapor cartridge and full facepiece.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations When using do not smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	Marker containing liquid ink
Physical state	Liquid.
Form	Liquid.
Color	Violet.
Odor	Slight characteristic odor. Isopropanol.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	87.0 °F (30.6 °C) Closed Cup
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	0.992
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
Incompatible materials	Acids. Strong oxidizing agents. Isocyanates. Chlorine.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause drowsiness and dizziness. Headache. Nausea, vomiting. Prolonged inhalation may be harmful.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Causes serious eye damage.
Ingestion	Expected to be a low ingestion hazard.
Symptoms related to the physical, chemical and toxicological characteristics	May cause drowsiness and dizziness. Headache. Nausea, vomiting. Irritation of nose and throat. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result.

Information on toxicological effects

Acute toxicity	Not expected to be acutely toxic.

Components	Species	Test Results
TRADE SECRET DYE (CAS Proprietary)		
Acute		
<i>Oral</i>		
LD50	Rat	420 mg/kg
TRADE SECRET SOLVENT (CAS Proprietary)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	12800 mg/kg 16.4 ml/kg, 24 Hours
<i>Inhalation</i>		
LC50	Rat	> 10000 ppm, 6 Hours
<i>Oral</i>		
LD50	Rat	5.84 g/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation	Causes serious eye damage.
Respiratory or skin sensitization	Not classified.
Respiratory sensitization	Not classified.
Skin sensitization	Not a skin sensitizer.
Germ cell mutagenicity	Not classified.
Carcinogenicity	Suspected of causing cancer.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity	Not classified.
Specific target organ toxicity - single exposure	May cause drowsiness and dizziness.

Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Chronic effects	Prolonged inhalation may be harmful.

12. Ecological information

Ecotoxicity	Toxic to aquatic life with long lasting effects.

Components	Species	Test Results
TRADE SECRET DYE (CAS Proprietary)		
Aquatic		
Fish	LC50 Medaka, high-eyes (<i>Oryzias latipes</i>)	0.1 mg/l, 48 hours
TRADE SECRET SOLVENT (CAS Proprietary)		
Aquatic		
Fish	LC50 Bluegill (<i>Lepomis macrochirus</i>)	> 1400 mg/l, 96 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Bioaccumulation is not expected.
Partition coefficient n-octanol / water (log Kow)	
TRADE SECRET DYE (CAS Proprietary)	0.51
TRADE SECRET SOLVENT (CAS Proprietary)	0.05
Mobility in soil	No data available for this product.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT	
UN number	UN1210
UN proper shipping name	Printing ink, flammable or Printing ink related material
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Label(s)	3
Packing group	III
Environmental hazards	
Marine pollutant	No
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Special provisions	B1, IB3, T2, TP1
Packaging exceptions	150
Packaging non bulk	173
Packaging bulk	242
IATA	
UN number	UN1210

UN proper shipping name	Printing ink, flammable or Printing ink related material
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Label(s)	3
Packing group	III
Environmental hazards	Yes
Special precautions for user	Read safety instructions, SDS and emergency procedures beforehandling.
IMDG	
UN number	UN1210
UN proper shipping name	Printing ink, flammable or Printing ink related material
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Label(s)	3
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	Not available.
Special precautions for user	Read safety instructions, SDS and emergency procedures beforehandling.
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

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. All components are on the U.S. EPA TSCA Inventory List. CERCLA/SARA Hazardous Substances - Not applicable.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not listed.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	Not listed.
SARA 311/312 Hazardous chemical	Yes
SARA 313 (TRI reporting)	Not regulated.
Other federal regulations	
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List	Not regulated.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)	Not regulated.
Safe Drinking Water Act (SDWA)	Not regulated.
US state regulations	This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US. Massachusetts RTK - Substance List

TRADE SECRET SOLVENT (CAS Proprietary)

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

TRADE SECRET SOLVENT (CAS Proprietary)

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

TRADE SECRET SOLVENT (CAS Proprietary)

US. Rhode Island RTK

TRADE SECRET SOLVENT (CAS Proprietary)

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

Not listed.

International Inventories

Country(s) or region	Inventory name	On inventory(yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates 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** 21-October-2014**Revision date** -**Version #** 01**NFPA ratings****References**

ACGIH
 EPA: AQUIRE database
 NLM: Hazardous Substances Data Base
 US. IARC Monographs on Occupational Exposures to Chemical Agents
 HSDB® - Hazardous Substances Data Bank
 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

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: 02/11/2016

SAFETY DATA SHEET**SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**

PRODUCT NAME: McKesson Topical Skin Adhesives - LIQUIBAND® flex™, LIQUIBAND® Exceed™, LIQUIBAND® Flow Control, LIQUIBAND®
MFR #: 122-2, 122-LBX, 122-LFC, 122-LQB

DISTRIBUTED BY: McKesson Medical-Surgical Inc.
 8741 Landmark Road
 Richmond, VA 23228

After September 1, 2015:
 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: Topical Skin Adhesive

SECTION 2: HAZARDS IDENTIFICATION

ROUTES OF ENTRY:

POTENTIAL HEALTH EFFECTS:

EYES: Category 2B

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: N/A

ACGIH: N/A

NTP: N/A

IARC: N/A

OTHER: N/A

SECTION 2 NOTES: N/A

SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS

INGREDIENT	CAS NO.	%	Exposure Limits
2-Octyl cyanoacrylate	133978-15-1	0-100	Not determined
n-Butyl cyanoacrylate	6606-65-1	0-100	Not determined

SECTION 3 NOTES: n-Butyl cyanoacrylate and 2-Octyl cyanoacrylate as individual compounds or blended together. These compounds compose the majority of the product. Other components in the formulation constitute a trade secret and occur in non-hazardous amounts.

SECTION 4: FIRST-AID MEASURES



SDS DATE: 02/11/2016

EYES: If eyelids are bonded, release eyelashes with a pad soaked in warm water. Cyanoacrylate that has bonded to eye protein will produce tears, which will assist in the debonding process. Keep eye covered with a wet pad until debonding is complete, usually within 1 to 3 days – do not force eye open. Seek medical advice if solid particles of cyanoacrylate are trapped behind eyelid – this may cause abrasive damage.

SKIN: Do not force separation. Peel or roll skin apart in warm soapy water using a blunt instrument such as a spoon. Pre-soaking in a solution of 5% sodium bicarbonate will assist separation.

INGESTION: Do not induce vomiting. Give 1 – 3 glasses of water to drink to dilute stomach contents. Do not give anything by mouth if victim is unconscious or convulsing. Obtain immediate medical attention. Saliva should lift adhesive in 12 to 48 hours. Avoid swallowing adhesive after detachment. Lips may become bonded together, apply copious amounts of warm water and encourage wetting/pressure from saliva inside mouth. Peel or roll lips apart gently. Call a physician.

INHALATION: Remove to fresh air. If symptoms persist, call a physician.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: N/A

SECTION 4 NOTES: N/A

SECTION 5: FIRE-FIGHTING MEASURES

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

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

AUTOIGNITION TEMPERATURE: 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: Water spray, CO₂, Foam, Dry Chemical

SPECIAL FIRE FIGHTING PROCEDURES: Wear full protective equipment including self-contained breathing apparatus

UNUSUAL FIRE AND EXPLOSION HAZARDS: Water may spread fire. Product floats on water when cured. Acrid smoke and irritating fumes (oxides of carbon – oxides of nitrogen) occur in fire conditions.

HAZARDOUS DECOMPOSITION PRODUCTS: Combustible by-products of carbon monoxide and dioxide

SECTION 5 NOTES: N/A

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: Wear appropriate protective clothing. Prevent material from entering drains and watercourses.

SECTION 6 NOTES: Use water spray to polymerise and scrape off floor. Solidified material may be scraped from surfaces for disposal.

SECTION 7: HANDLING AND STORAGE

HANDLING: Avoid contact with eyes, skin and clothing. Avoid inhaling vapours on application.

STORAGE: Avoid moisture, direct UV sunlight and prolonged storage above 25°C (77°F).

OTHER PRECAUTIONS: N/A

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION



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ENGINEERING CONTROLS:**VENTILATION:** Local exhaust to prevent eye irritation**RESPIRATORY PROTECTION:** Normally not necessary. A NIOSH approved organic vapour cannister may be used.**EYE PROTECTION:** Chemical goggles, safety glasses with side shields.**SKIN PROTECTION:** Chemical resistant gloves – polyethylene recommended.**OTHER PROTECTIVE CLOTHING OR EQUIPMENT:** Rubber apron.**WORK HYGIENIC PRACTICES:** N/A**EXPOSURE GUIDELINES:** N/A**SECTION 8 NOTES:** N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Violet or colourless liquid, slightly pungent/sharp odor.**PHYSICAL STATE:****pH AS SUPPLIED:** N/A**pH (Other):** N/A**BOILING POINT:** 302°F**MELTING POINT:** Not determined**FREEZING POINT:** Not determined**VAPOR PRESSURE (mmHg):** Not determined

@ N/A

DENSITY (lb/gal):

@ N/A

SPECIFIC GRAVITY (H₂O = 1): N/A

@ N/A

EVAPORATION RATE: Not determined**BASIS (=1):** N/A**SOLUBILITY IN WATER:** Negligible in water (polymerises)**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:** <100cP**SECTION 9 NOTES:** N/A

SECTION 10: STABILITY AND REACTIVITY

STABLE**UNSTABLE****STABILITY:** Stable



SDS DATE: 02/11/2016

CONDITIONS TO AVOID (STABILITY): Temperatures >38°C (100°F)**INCOMPATIBILITY (MATERIAL TO AVOID):** Amines, Alcohols, Water, cotton, wool bases**HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:** Combustible by-products of carbon monoxide and dioxide**HAZARDOUS POLYMERIZATION:** Hazardous polymerisation may not occur**CONDITIONS TO AVOID (POLYMERIZATION):** N/A**SECTION 10 NOTES:** N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: Cyanoacrylate vapours are irritating to eyes and mucous membranes; prolonged and repeated overexposure may result in allergic reactions (rhinitis) with asthma-like symptoms in certain individuals. In the event of fire or heating, cyanoacrylate adhesives increase their volatility and this increases the risk of respiratory irritation and sensitisation. Contact dermatitis may occur after chronic repetitive exposure of the skin to liquid monomer. Weeping, tears and double vision may be experienced until polymerisation has occurred. If cured cyanoacrylate enters the eye, there is a chance of corneal damage due to abrasion. Irritation with pain, corneal abrasions, keratoconjunctivitis and eyelash loss occurs. Pre-existing skin, eye and respiratory disorders may be aggravated by exposure. The vapour is irritating to eyes and mucous membranes. Prolonged and repeated overexposure to vapours may produce allergic reactions with asthma-like symptoms in sensitive individuals

SECTION 11 NOTES:

This product is not expected to cause long-term adverse health effects.

This product is not expected to cause reproductive and developmental health effects.

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: N/A**SECTION 12 NOTES:** N/A

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: This product is not a hazardous waste. Flood with water to polymerise. Soak up with an inert absorbent (earth or sand). Dispose of in an approved landfill in accordance with local authority regulations.

RCRA HAZARD CLASS: N/A**SECTION 13 NOTES:** N/A

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION**PROPER SHIPPING NAME:** N/A**HAZARD CLASS:** N/A**DOT SHIPPING ID NUMBER:** N/A**DOT PACKING GROUP:** N/A**DOT 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



SDS DATE: 02/11/2016

ID NUMBER: N/A
PACKING GROUP: N/A
LABEL STATEMENTS: N/A

SECTION 14 NOTES: Not restricted for transportation by air, sea, and road.

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TSCA (TOXIC SUBSTANCE CONTROL ACT): N/A

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

SARA 311/312 HAZARD CATEGORIES: N/A

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

STATE REGULATIONS: N/A

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: 11/11/2015

SAFETY DATA SHEET**SECTION 1: PRODUCT AND COMPANY IDENTIFICATION****PRODUCT NAME:** McKesson Triple Antibiotic ointment**MFR #:** 118-42213**DISTRIBUTED BY:**

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

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

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

PRODUCT DESCRIPTION: First aid antibiotic**SECTION 2: HAZARDS IDENTIFICATION****ROUTES OF ENTRY:** Topical

POTENTIAL HEALTH EFFECTS: This is a pharmaceutical material available without a prescription- use only as directed. See product packaging for further information concerning adverse effects and drug interaction precautions.

EYES: May cause irritation with symptoms of reddening, tearing and stinging.

SKIN: Allergy to any ingredient may cause anaphylactic shock.

INGESTION: Symptoms of ingestion may include abdominal pain, nausea, vomiting, and diarrhea.

INHALATION: Not applicable.

ACUTE HEALTH HAZARDS: The chief health hazard associated with exposure during normal use and handling is the potential for irritation of contaminated skin. Individuals who have had allergic reactions to products containing Aminoglycosides or any other components of this product may experience allergic reactions to this product. Allergic reactions may be severe and can be life-threatening in certain individuals.

CHRONIC HEALTH HAZARDS: Stop use and ask a doctor if condition worsens symptoms persist more than 7 days or clear up and occur again in a few days.

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: Pre-existing skin conditions may be aggravated by repeated overexposures to this product.

CARCINOGENICITY**OSHA:** Not listed**ACGIH:** Not listed**NTP:** Not listed**IARC:** Not listed**OTHER:** N/A

SECTION 2 NOTES: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to the manufacturer's directions.



SDS DATE: 11/11/2015

SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS

<u>INGREDIENT</u>	<u>CAS NO.</u>	<u>%</u>	<u>Exposure Limits</u>
Petrolatum	8009-03-8	10-100	
Neomycin sulfate	1405-10-3	0.1-1	
Polymyxin B sulfate	1405-20-5	0.01-0.1	
Bacitracin zinc	1405-89-6	0.1-1	

SECTION 3 NOTES: The formulations for these products are proprietary information. Inactive ingredients of less than 1% not displayed above.

SECTION 4: FIRST-AID MEASURES

EYES: In case of contact, flush with copious amounts of water for at least 15 minutes. Call a physician.

SKIN: If adverse skin effects occur, discontinue use. Seek medical attention.

INGESTION: In case of accidental ingestion, contact your regional poison center or physician immediately.

INHALATION: Not applicable.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure.

SECTION 4 NOTES: Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of label and SDS to physician or health professional with the contaminated individual.

SECTION 5: FIRE-FIGHTING MEASURES

FLAMMABLE LIMITS IN AIR, UPPER: Not Established
(% BY VOLUME) **LOWER:** Not Established

FLASH POINT: Not Established

METHOD USED: N/A

AUTOIGNITION TEMPERATURE: Not Established

NFPA HAZARD CLASSIFICATION

HEALTH: 2 **FLAMMABILITY:** 1 **REACTIVITY:** 0 **OTHER:** N/A

HMIS HAZARD CLASSIFICATION

HEALTH: 2 **FLAMMABILITY:** 1 **REACTIVITY:** N/A **PERSONAL:** 0

EXTINGUISHING MEDIA: Water Fog, Sand, Earth, Dry Chemical, Foam

SPECIAL FIRE FIGHTING PROCEDURES: Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

UNUSUAL FIRE AND EXPLOSION HAZARDS: None known.

HAZARDOUS DECOMPOSITION PRODUCTS: None known.

SECTION 5 NOTES: See section 9 for physical and chemical properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: Use appropriate personal protective equipment during clean up. Scrape or shovel material. Use oil absorbent rags.

SECTION 6 NOTES: See Sections 9 and 10 for additional physical, chemical and hazard information.



SDS DATE: 11/11/2015

SECTION 7: HANDLING AND STORAGE

HANDLING: Keep this and all drugs out of the reach of children. Avoid contact with eyes.

STORAGE: Store in a dry place away from excessive heat, in original or similar waterproof containers. Use normal precautions for storage of a drug.

OTHER PRECAUTIONS: Follow SPECIFIC USE INSTRUCTIONS supplied with this product.

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

VENTILATION: None Required.

RESPIRATORY PROTECTION: None Required.

EYE PROTECTION: Eye protection, as necessary to prevent excessive contact.

SKIN PROTECTION: None required when used as intended.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

WORK HYGIENIC PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product.

EXPOSURE GUIDELINES: Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of label and SDS to physician or health professional with the contaminated individual.

SECTION 8 NOTES: This guidance applies to the handling of the active ingredient(s) in this formulation. The end-user should perform an appropriate risk assessment when handling other forms or formulations of this active ingredient.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: yellow to off-white, nearly odorless

PHYSICAL STATE: ointment

pH AS SUPPLIED: N/A

pH (Other): N/A

BOILING POINT: Not Established

MELTING POINT: Not Established

FREEZING POINT: Not Established

VAPOR PRESSURE (mmHg): Not Established

DENSITY (lb/gal): Not Established

SPECIFIC GRAVITY (H₂O = 1): 0.8

EVAPORATION RATE: Not Established

BASIS (=1): N/A

SOLUBILITY IN WATER: Not soluble

PERCENT SOLIDS BY WEIGHT: Not Established

PERCENT VOLATILE: Not Established

BY WT/ N/A BY VOL @ N/A

VOLATILE ORGANIC COMPOUNDS (VOC): Not Established

WITH WATER: N/A **LBS/GAL**

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

MOLECULAR WEIGHT: Not Established

VISCOSITY: Not Established

SECTION 9 NOTES: See Section 5 for flammability/explosivity information.



SDS DATE: 11/11/2015

SECTION 10: STABILITY AND REACTIVITY

STABLE**UNSTABLE****STABILITY:** X**CONDITIONS TO AVOID (STABILITY):** Avoid excessive heat and light**INCOMPATIBILITY (MATERIAL TO AVOID):** Oxidizing agents**HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:** Carbon oxides, nitrogen oxides, and sulfur oxides.**HAZARDOUS POLYMERIZATION:** Will not occur**CONDITIONS TO AVOID (POLYMERIZATION):** N/A**SECTION 10 NOTES:** N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: No data available for this product.**SECTION 11 NOTES:** This information pertains to the formulated product unless indicated otherwise.

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: This product has not been tested for Eco toxicity.**SECTION 12 NOTES:** There is no environmental data available for this product.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incarceration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: Disposal must be in accordance with federal, state/provincial, and/or local regulations.

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION

PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
DOT SHIPPING ID NUMBER: N/A
DOT PACKING GROUP: N/A
DOT HAZARD CLASS: N/A
DOT LABEL STATEMENT: N/A

WATER TRANSPORTATION

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

AIR TRANSPORTATION

PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
ID NUMBER: N/A



SDS DATE: 11/11/2015

PACKING GROUP: N/A
LABEL STATEMENTS: N/A

SECTION 14 NOTES: This material is not subject to the transportation regulations of DOT, IATA, and the ADR.

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TSCA (TOXIC SUBSTANCE CONTROL ACT): Exempt

CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): Not listed

SARA 311/312 HAZARD CATEGORIES: N/A

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

STATE REGULATIONS: When used internally, the Neomycin Sulfate component of this product is on the California Proposition 65 lists as a compound that is known to cause developmental harm.

INTERNATIONAL REGULATIONS: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

SECTION 15 NOTES: For details on your regulatory requirements you should contact the appropriate agency in your state.

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A

PREPARATION INFORMATION:

SDS CREATION DATE: November 11, 2015

SDS VERSION: Original

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



SDS DATE: 11/11/2015

SAFETY DATA SHEET**SECTION 1: PRODUCT AND COMPANY IDENTIFICATION****PRODUCT NAME:** McKesson Ultrasound Gel-Pink**MFR #:** 4961 (8.5 oz bottle); 4962 (5 L bottle)**DISTRIBUTED BY:** McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, VA 23233**INFORMATION LINE:** 1-800-777-4908 Monday – Friday 8:00 a.m. – 6:00 p.m. EST**EMERGENCY PHONE:** 1-800-451-8346 (3E Company) Day or Night**PRODUCT DESCRIPTION:** N/A**SECTION 2: HAZARDS IDENTIFICATION****ROUTES OF ENTRY:** May cause redness to the eyes**POTENTIAL HEALTH EFFECTS:****EYES:****SKIN:****INGESTION:** May cause upset stomach if ingested**INHALATION:****ACUTE HEALTH HAZARDS:****CHRONIC HEALTH HAZARDS:****MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE:****CARCINOGENICITY****OSHA:** N/A**ACGIH:** N/A**NTP:** N/A**IARC:** N/A**OTHER:** N/A**SECTION 2 NOTES:** N/A**SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS**

<u>INGREDIENT</u>	<u>CAS NO.</u>	<u>%</u>	<u>Exposure Limits</u>

SECTION 3 NOTES: This product is known to be a non-hazardous product.**SECTION 4: FIRST-AID MEASURES****EYES:** Flush with water for 15 minutes while holding eyelids open. Seek medical attention if irritation persists.**SKIN:****INGESTION:** Induce vomiting. Seek medical attention.**INHALATION:**



SDS DATE: 11/11/2015

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:

SECTION 4 NOTES: N/A

SECTION 5: FIRE-FIGHTING MEASURES

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

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

AUTOIGNITION TEMPERATURE: 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:**SPECIAL FIRE FIGHTING PROCEDURES:****UNUSUAL FIRE AND EXPLOSION HAZARDS:****HAZARDOUS DECOMPOSITION PRODUCTS:****SECTION 5 NOTES:** Non-flammable

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: Scoop up excess. Clean with appropriate cleaner and rinse with water.**SECTION 6 NOTES:** N/A

SECTION 7: HANDLING AND STORAGE

HANDLING: No special requirements**STORAGE:** Store away from heat and extreme cold**OTHER PRECAUTIONS:** N/A**SECTION 7 NOTES:** N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:**VENTILATION:****RESPIRATORY PROTECTION:****EYE PROTECTION:****SKIN PROTECTION:****OTHER PROTECTIVE CLOTHING OR EQUIPMENT:** N/A**WORK HYGIENIC PRACTICES:****EXPOSURE GUIDELINES:** N/A



SDS DATE: 11/11/2015

SECTION 8 NOTES: N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Essentially odorless, viscous, clear, aqueous, pink in color**PHYSICAL STATE:** Liquid**pH AS SUPPLIED:** 6.5—7.5**pH (Other):** N/A**BOILING POINT:** 100°C**MELTING POINT:** N/A**FREEZING POINT:** N/A**VAPOR PRESSURE (mmHg):** N/A

@ N/A

DENSITY (lb/gal): N/A

@ N/A

SPECIFIC GRAVITY (H₂O = 1): 1.03

@ N/A

EVAPORATION RATE: N/A**BASIS (=1):** N/A**SOLUBILITY IN WATER:** Good**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: N/A

SECTION 10: STABILITY AND REACTIVITY

STABLEUNSTABLE**STABILITY:** X**CONDITIONS TO AVOID (STABILITY):****INCOMPATIBILITY (MATERIAL TO AVOID):****HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:****HAZARDOUS POLYMERIZATION:****CONDITIONS TO AVOID (POLYMERIZATION):** N/A

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: N/A



SDS DATE: 11/11/2015

SECTION 11 NOTES: N/A

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: N/A

SECTION 12 NOTES: N/A

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of in accordance with local, state and federal regulations.

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION

PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
DOT SHIPPING ID NUMBER: N/A
DOT PACKING GROUP: N/A
DOT 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): N/A

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

SARA 311/312 HAZARD CATEGORIES: N/A

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

STATE REGULATIONS: N/A

INTERNATIONAL REGULATIONS: N/A

SECTION 15 NOTES: N/A

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A



SDS DATE: 11/11/2015

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.



McKesson Medical-Surgical, Inc. • 9954 Mayland Drive, Suite 4000 • Richmond, Virginia 23233 • Tel. 800-777-4908
McKesson Brands Help Desk: mckessonbrands@mckesson.com

DATE: February 3, 2016

Product: McKesson UPS Sterile Water and McKesson UPS Normal Saline

MFR #: 37-6210, 37-6250, 37-6260 and 37-6290 (McKesson UPS Sterile Water)
37-6220, 37-6240, 37-6270 and 37-6280 (McKesson UPS Normal Saline)

Dear Customer:

This product does not meet the definition of a hazardous chemical as defined by the Occupational Health & Safety Administration (OSHA) 21 CFR 1910.1200 and does not require a Safety Data Sheet.

Sincerely,

McKesson Brands
McKesson Medical-Surgical, Inc.



SAFETY DATA SHEET

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

Product Identifier

Material Name: Methylprednisolone Acetate Suspension, USP, Sterile

Trade Name: Depo-Medrol
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as anti-inflammatory

Details of the Supplier of the Safety Data Sheet

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

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

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

Label Elements

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

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

SAFETY DATA SHEET

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**Other Hazards**

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

Note:

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

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

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

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

Additional Information:

* Proprietary

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

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

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

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

Skin Contact:

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

Ingestion:

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

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Suspension, USP,
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Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

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

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: May include oxides of carbon.

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

Advice for Fire-Fighters

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

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

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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

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

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

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

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Benzyl Alcohol

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

Methylprednisolone Acetate

Pfizer OEL TWA-8 Hr: 4µg/m³, Skin

Polyethylene glycol

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

Sodium phosphate, dibasic

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

Sodium phosphate, monobasic

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

Exposure Controls**Engineering Controls:**

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

Personal Protective Equipment:

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

Hands:

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

Eyes:

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

Skin:

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

Respiratory protection:

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

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9. PHYSICAL AND CHEMICAL PROPERTIES

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

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

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

Methylprednisolone Acetate

No data available

Methylprednisolone

Predicted 7.4 Log D 1.99

Water

No data available

Polyethylene glycol

No data available

Polysorbate 80

No data available

Sodium phosphate, dibasic

No data available

Sodium phosphate, monobasic

No data available

Benzyl Alcohol

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

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

Flammability (Solids): No data available

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

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

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

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

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

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

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10. STABILITY AND REACTIVITY

Hazardous Decomposition Products: No data available

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

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

Short Term:

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

Long Term:

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

Known Clinical Effects:

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

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

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

Methylprednisolone

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

Polysorbate 80

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

Benzyl Alcohol

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

Acute Toxicity Comments:

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

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

Eye Irritation Rabbit No effect
Skin Irritation Rabbit No effect

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11. TOXICOLOGICAL INFORMATION**Methylprednisolone**

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

Polyethylene glycol

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Benzyl Alcohol

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

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

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

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

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

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

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

Methylprednisolone

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

Carcinogen Status:

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

SAFETY DATA SHEET

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12. ECOLOGICAL INFORMATION

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

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

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

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

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

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

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

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

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

Bio-accumulative Potential: No data available

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

Predicted 7.4 Log D 1.99

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

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

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15. REGULATORY INFORMATION

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

Benzyl Alcohol

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

Methylprednisolone Acetate

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

Polyethylene glycol

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

Polysorbate 80

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

Sodium phosphate, dibasic

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

Sodium phosphate, monobasic

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

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Suspension, USP,
Sterile
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15. REGULATORY INFORMATION**Water**

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

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

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

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

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

Revision date: 23-Mar-2017

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

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

Issuing Date 29-Nov-2009

Revision Date 14-Jan-2018

Revision Number 1

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

1.1. Product identifier

Product Name	METHYLPREDNISOLONE SODIUM SUCCINATE
Chemical Name	Pregna-1,4-diene-3,20-dione, 21-(3-carboxy-1-oxopropoxy)-11,17-dihydroxy-6-methyl-, monosodium salt, (6a, 11b)
Synonyms	A-methaPred; MPS; Solu-Medrol; Urabason
Formula	C ₂₆ H ₃₃ Na O ₈
CAS	2375-03-3
EINECS	219-156-8
Index No	No information available
Reach Registration Number	No information available

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

Identified uses	Active Pharmaceutical Ingredient
Uses advised against	No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer, Supplier	Teva API Japan, Ltd.
	Metro City Kamiyacho Bldg. 7F, 5-1-5, Toranomon, Minato-ku
	Tokyo
	105-0001
	Japan
	+81 354048441

For further information, please contact

E-mail Address SDS.TevaLL@teva.co.il

1.4. Emergency Telephone Number

Emergency Telephone Number	United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs] International: 01-703-527-3887 (Chemtrec) [24-hours]

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Repr. 1B H360D

STOT RE 2 H373

Full text of H-Statements referred to under section 16

2.2. 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

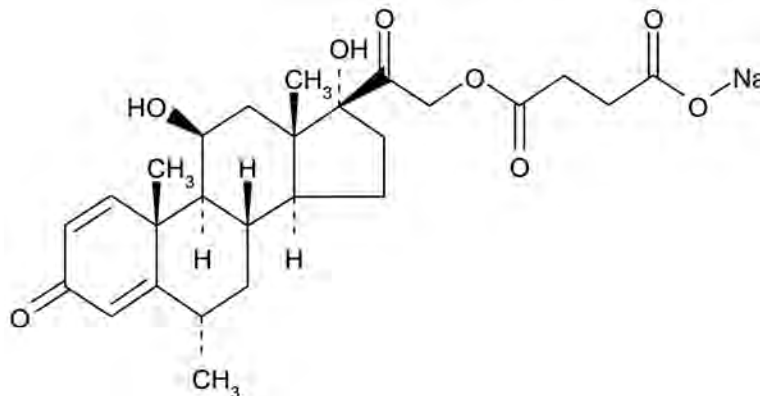
P260 - Do not breathe dust

P312 - Call a POISON CENTER or doctor/physician if you feel unwell

P262 - Do not get in eyes, on skin, or on clothing

2.3. Other hazards

None known

SECTION 3: Composition/information on ingredients**3.1. Substances**

Chemical Name	EC No	REACH Reg. No	CAS No	Weight-%
Pregna-1,4-diene-3,20-dione 21-(3-carboxy-1-oxopropoxy)-11,17-dihydroxy-6-methyl-, monosodium salt, (6a, 11b)	EEC No. 219-156-8	Not available	2375-03-3	100

3.2. Mixtures

N.A.

SECTION 4: First aid measures**4.1. Description of first aid measures**

Eye Contact	Flush eyes with water for at least 15 minutes. Get medical attention if eye irritation develops or persists.
Skin Contact	Wash off immediately with plenty of water. Get medical advice/attention if you feel unwell.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Get medical advice/attention if you feel unwell.
Inhalation	Remove person to fresh air. If signs/symptoms continue, get medical attention.

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

Irritation	Skin, Non-irritant, Animal evidence.
Corrosivity	No information available.
Eyes	May cause, irritation.
Skin	May cause, skin rash, discoloration of skin.
Inhalation	May cause, Itching.
Ingestion	May cause: Pain.
Notes to Physician	Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Foam. Dry extinguishing powder. Halons.

Unsuitable extinguishing media

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.

5.3. Advice for firefighters

Special protective equipment for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protection equipment. Avoid breathing of or direct contact with material.

6.1.1. For non-emergency personnel

Protective equipment See section 8

Emergency procedures Ensure response by people trained and equipped to respond to incidents with the potential to become emergencies, or evacuate the area until professional emergency responders or fire department arrives

6.1.2. For emergency responders

See section 8

6.2. Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so. Local authorities should be advised if significant spillages cannot be contained.

6.3. Methods and material for containment and cleaning up Methods and materials for containment and cleaning up

6.3.1. Methods for Containment

No information available.

6.3.2. For cleaning up

Sweep up and shovel into suitable containers for disposal. Prevent dust cloud.

6.3.3. Other information

No information available

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for Safe Handling

Handling

Avoid contact with skin, eyes or clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Use exhaust ventilation to keep airborne concentrations below exposure limits. Follow general hygiene considerations recognized as common good workplace practices.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Keep in properly labeled containers. See product quality documents and/or label for the correct storage conditions of this product.

7.3. Specific end use(s)

Exposure scenario

No information available.

Other Guidelines

No information available.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Exposure Limits** Teva OEL Range: $100 > x \geq 10 \mu\text{g}/\text{m}^3$ **Biological occupational exposure limits** No information available.**Derived No Effect Level (DNEL)** No information available.**Predicted No Effect Concentration (PNEC)** No information available.**8.2. Exposure controls****Engineering Measures**

Appropriate Engineering Controls.

Personal protective equipment**Eye/face protection**

Wear appropriate eye protection to prevent eye contact.

Skin protection:

- Body protection

Wear appropriate personal protective clothing to prevent skin contact.

- Hand protection

Wear suitable gloves.

Respiratory Protection

In case of inadequate ventilation wear respiratory protection.

Environmental exposure controls Ensure adequate ventilation, especially in confined areas.**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties****Appearance****Color**

White Off-white

Physical State

crystalline powder Hygroscopic

Odor

odorless

Odor Threshold

No information available

pH

No information available

Melting Point / Melting Range

No information available

Boiling point / boiling range

No information available

Flash Point

No information available

Evaporation Rate

No information available

Flammability (solid, gas)

No information available

Flammability Limit in Air**Upper**

No information available

Lower

No information available

Vapor Pressure

No information available

Vapor Density

No information available

Relative Density

No information available

Solubility

Soluble in Alcohol Very Slightly soluble in Acetone Insoluble in Chloroform Ether

Water Solubility

Soluble in water

Autoignition Temperature

No information available

Decomposition Temperature

No information available

Viscosity

No information available

Explosive Properties

No information available

Oxidizing Properties

No information available

9.2. Other information**Molecular Weight**

496.54

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical Stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization does not occur.

10.4. Conditions to avoid

Heat, flames and sparks.

10.5. Incompatible materials.

Strong oxidizing agents.

10.6. Hazardous decomposition products

Toxic fumes of, Carbon monoxide (CO), Carbon dioxide (CO₂).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute Toxicity

LD₅₀ (Oral, Rat, mg/kg) > 4000 mg/kg

LD₅₀ Subcutaneous rat > 3000 mg/kg

LD₅₀ Intraperitoneal rat 1000 mg/kg

LD₅₀ Intraperitoneal mouse 1409 mg/kg

Skin Corrosion/Irritation No information available.

serious eye damage/irritation No information available.

respiratory or skin sensitization No information available.

Germ Cell Mutagenicity

No mutagenic or clastogenic effects were found.

carcinogenicity

Not listed by IARC, NTP and OSHA. No data available.

reproductive toxicity

Positive. Animal data.

STOT - single exposure

No information available.

STOT - repeated exposures

No information available.

aspiration hazard

No information available.

Other Information

Body as a whole

May cause: Allergic reactions.

SECTION 12: Ecological information**12.1. Toxicity****Ecotoxicity effects**

No information available.

12.2. Persistence and degradability

Hazard of persistence may be possible.

12.3. Bioaccumulative potential

Bioaccumulation may be possible.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Waste from Residues/Unused
Products**

Dispose of in accordance with local regulations.

Contaminated Packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information**14.1.****UN-No**

-

14.2.**Proper Shipping Name**

-

14.3. Transport hazard class(es)**Land transport (ADR/RID)**

-

Sea transport (IMDG)

-

Air transport (ICAO-TI / IATA-DGR)

-

14.4.**Packing Group**

-

14.5. Environmental hazards**Marine Pollutant**

-

14.6. Special precautions for user**Emergency No.**

-

ADR/RID-Labels

-

14.7.**Technical name**

-

Ship type

-

Annex II

-

AL_DM_IT301JP
METHYLPREDNISOLONE SODIUM SUCCINATE

Revision Date 14-Jan-2018

SECTION 15: Regulatory information

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

- Regulation 1907/2006/EC (REACH) and successive modifications
- Regulation 1272/2008 (CLP) and successive modifications
- D.Lgs. 81/2008 and successive modifications and Dir. 2009/161/EU
- REGULATION (EU) 2015/830

This safety data sheet complies with the requirements of: GHS

15.2. Chemical Safety Assessment

No information available

SECTION 16: Other information

CLP/GHS - Regulation

Hazard Statements

H360D - May damage the unborn child

H373 - May cause damage to organs through prolonged or repeated exposure

Training appropriate for workers is required to ensure protection of human health and environment.

Source of data

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES

A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS

H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK

N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

N.T.P. - NATIONAL TOXICOLOGY PROGRAM

I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

ECHA (European chemicals agency) databases

FDA (Food & Drug administration) database

EMA (European Medicines agency) documents

ChemAdvisor

Chemspider database

Issuing Date 29-Nov-2009

Revision Date 14-Jan-2018

Revision Note

Not applicable

Disclaimer

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

End of Safety Data Sheet



Safety Data Sheet

Monsel's Solution

Revision Date: 06/15/15

1. PRODUCT AND COMPANY IDENTIFICATION

- 1.1 Product identifier** Trade Name: Monsel's Solution
Product code(s): 400490, 400491, 400500, 400599
- 1.2 Relevant identified use** Laboratory Reagent
- 1.3 Supplier** Company: HealthLink, Inc
3611 St Johns Bluff Road, Suite 1
Jacksonville, FL 32224
800-638-2625
Monday-Friday: 8:00 -5:00 PM
- 1.4 Emergency Telephone** CHEMTREC 800.424.9300

2. COMPONENT AND HAZARDS IDENTIFICATION

2.2 Classification of the substance or mixture

Hazard statement: Not a dangerous substance according to the Globally Harmonized System (GHS).

2.3 GHS Label elements, including precautionary statements: Not listed



Precautionary statement(s):

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.
Skin: Wear protective gloves/ eye protection/ face protection.
Ingestion: May be harmful if swallowed. Call a doctor/ physician.
If in eyes: May cause irritation. Rinse cautiously with water for several minutes.

2.4 WHMIS Classification

Not classified

2.5 NFPA Rating

Health hazard: 0
Fire: 0
Reactivity Hazard: 0

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Components	Name	CAS number	% by weight
	Ferric Subsulfate Solution	1310-45-8	20-22
	Water	7732-18-5	78-80

4. FIRST AID MEASURES

4.1 General Information

Eye contact:	Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical attention immediately.
Skin contact:	In case of contact, flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Clean shoes thoroughly before reuse. Get medical attention immediately.
Inhalation:	Move exposed person to fresh air. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention immediately.
Ingestion:	Call medical doctor or poison control center immediately. Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention immediately.

5. FIREFIGHTING MEASURES

5.1 Extinguishing media:	Use an extinguishing agent suitable for the surrounding fire.
5.2 Special hazards:	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
5.3 Hazardous Thermal decomposition products:	In fire situation SO ₂ can be released
5.4 Special protective equipment for fire-fighters:	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions:	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Do not breathe vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see Section 8).
6.2 Environmental precaution:	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
6.3 Clean up:	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container

for disposal according to local regulations (see section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see section 1 for emergency contact information and section 13 for waste disposal. Dilute with water and mop up if water-soluble or absorb with an inert dry material and place in an appropriate waste disposal container.

7. HANDLING AND STORAGE

- 7.1 Safe Handling:** Do not get in eyes, on skin or clothing. Do not breathe vapor or mist. Do not ingest. Use only with adequate ventilation. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Use empty containers to retain product, residue can be hazardous. Do not reuse container.
- 7.2 Storage:** Store in a segregated and approved area protected from frost. Protect from direct sunlight. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Consult local authorities for acceptable exposure limits.

8.2 Engineering measures: Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

8.3 Hygiene measures: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing.

8.4 Personal protection

Respiratory: Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Hands: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Recommended: neoprene

Eyes: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts. Recommended: splash goggles

Skin: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Recommended: lab coat

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

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state: Liquid. **Color:** Brownish/red

Odor:	Odorless	pH:	NA
Boiling/condensation point:	100°C (212°F)	Melting/freezing point:	Not available
Relative density:	1.5 g/mL	Vapor pressure:	Not available
Vapor density:	Not available	Odor threshold:	Not available
Evaporation rate:	NA	Solubility:	Soluble in water

10. STABILITY AND REACTIVITY

10.1 Chemical stability: The product is stable.

10.2 Possibility of hazardous reactions: Under normal conditions of storage and use, hazardous reactions will not occur.

10.3 Hazardous polymerization: Under normal conditions of storage and use, hazardous polymerization will not occur.

10.4 Conditions to avoid: No specific data

10.5 Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not occur. In fire situation product may liberate SO₂.

11. TOXICOLOGICAL INFORMATION

Carcinogenicity: No known significant effects or critical hazards.

Mutagenicity: No known significant effects or critical hazards.

Teratogenicity: No known significant effects or critical hazards

12. ECOLOGICAL INFORMATION

12.1 Environmental Precautions: No known significant effects or critical hazardous. The products of degradation are less toxic than the product itself. Water hazard class 1 (self assessment)

13. DISPOSAL CONSIDERATIONS

13C.1 Methods: The information presented only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national, local laws and regulations.

14. TRANSPORT INFORMATION

Not regulated

15. REGULATORY INFORMATION

United States

HCS Classification: Not regulated

U.S. Federal regulations: **TSCA 8(a) IUR:** Not listed
United States inventory (TSCA 8b): ferric subsulfate
 All components are listed or exempted.

All components of this product are listed on or compliant with the TSCA inventory.
SARA 302/304/311/312 extremely hazardous substances: No products were found.
SARA 302/304 emergency planning and notification: No products were found.
SARA 302/304/311/312 hazardous chemicals: No products were found.
SARA 311/312 MSDS distribution - chemical inventory - hazard identification:
 No products were found.
 Clean Water Act (CWA) 307: No products were found.
 Clean Water Act (CWA) 311: No products were found.
Clean Air Act (CAA) 112 accidental release prevention: No products were found.
 Clean Air Act (CAA) 112 regulated flammable substances: No products were found.
 Clean Air Act (CAA) 112 regulated toxic substances: No products were found.

DEA List I & II Chemicals

(Precursor Chemicals): Not listed

Connecticut Carcinogen Reporting: None of the components are listed.
Florida substances: None of the components are listed.
Massachusetts Substances: None of the components are listed.
Minnesota Hazardous Substances: None of the components are listed.
New Jersey Hazardous Substances: None of the components are listed.
NY Toxic Chemical Release Reporting: None of the components are listed.
New York Acutely Hazardous Substances: None of the components are listed.
Pennsylvania RTK Hazardous Substances: None of the components are listed.
Rhode Island Hazardous Substances: None of the components are listed.

WHMIS (Canada):

Not controlled

Canadian lists:

CEPA Toxic substances: None of the components are listed.
Canadian ARET: None of the components are listed.
Canadian NPRI: None of the components are listed.
Alberta Designated Substances: None of the components are listed.
Ontario Designated Substances: None of the components are listed.
Quebec Designated Substances: None of the components are listed.

CEPA DSL / CEPA NDSL:

All components are listed or exempted.

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

International regulations

International lists:

Australia inventory (AICS): All components are listed or exempted.
China inventory (IECSC): All components are listed or exempted.
Japan inventory: Not determined.
Korea inventory: Not determined.
New Zealand Inventory of Chemicals (NZIoC): All components are listed or exempted.
Philippines inventory (PICCS): All components are listed or exempted.

16. OTHER INFORMATION



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

Disclaimer

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Healthlink shall not be liable for any damage resulting from handling.



SAFETY DATA SHEET

Revision date: 09-Aug-2016

Version: 1.0

Page 1 of 10

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

Product Identifier

Material Name: Nalbuphine Hydrochloride Injection (Hospira Inc.)

Trade Name: Nalbuphine Hydrochloride Injection
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as analgesic

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
 275 North Field Drive
 Lake Forest, Illinois 60045
 1-800-879-3477

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

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

Note:

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

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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)	**
Nalbuphine Hydrochloride	23277-43-2	245-549-9	Acute Tox 4 (H302)	1-2

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	*
Sodium Citrate	6132-04-3	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 CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:	Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
Skin Contact:	Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
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: As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture

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Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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

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

7. HANDLING AND STORAGE

Precautions for Safe Handling

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

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
Spain OEL - TWA	5 ppm
	7.6 mg/m ³

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Material Name: Nalbuphine Hydrochloride Injection (Hospira Inc.)

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL - TWAs	2 ppm 3.0 mg/m ³
Vietnam OEL - TWAs	5 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.

Nalbuphine Hydrochloride

Pfizer Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
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:	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:	3.0-4.5		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
Water for Injection			
No data available			
Nalbuphine Hydrochloride			
No data available			
Sodium Citrate			
No data available			

SAFETY DATA SHEET

Material Name: Nalbuphine Hydrochloride Injection (Hospira Inc.)

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9. PHYSICAL AND CHEMICAL PROPERTIES

Citric acid, anhydrous

No data available

SODIUM HYDROXIDE

No data available

HYDROCHLORIC ACID

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

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

Flammability (Solids): No data available

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

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

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

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: None

Conditions to Avoid: Not determined

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

Hazardous Decomposition Products: Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

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: Use of this drug is habit forming. Addiction may occur.

Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include dizziness, dry mouth, vertigo, sedation, headache, sweating, nausea, vomiting, respiratory depression, symptoms of dependence/withdrawal.

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

Nalbuphine Hydrochloride

Dog Oral LD50 1100 mg/kg

Dog IV LD50 140mg/kg

Citric acid, anhydrous

Rat Oral LD50 3000 mg/kg

SAFETY DATA SHEET

Material Name: Nalbuphine Hydrochloride Injection (Hospira Inc.)

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11. TOXICOLOGICAL INFORMATION

HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

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

Citric acid, anhydrous

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Nalbuphine Hydrochloride

Reproductive & Fertility Rat Subcutaneous 56 mg/kg/day NOAEL No effects at maximum dose

Embryo / Fetal Development Rat Subcutaneous 100 mg/kg/day NOAEL Not Teratogenic

Embryo / Fetal Development Rabbit Subcutaneous 32 mg/kg/day NOAEL Not Teratogenic

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

Nalbuphine Hydrochloride

Bacterial Mutagenicity (Ames) Bacteria Negative

HGPRT Forward Gene Mutation Assay Chinese Hamster Ovary (CHO) cells Negative

Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative

Mammalian Cell Mutagenicity Mouse Lymphoma Positive

In Vivo Micronucleus Mouse Negative

HYDROCHLORIC ACID

Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vivo Micronucleus Rat Negative

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

Nalbuphine Hydrochloride

24 Month(s) Rat Oral 200 mg/kg/day NOAEL Not carcinogenic

19 Month(s) Mouse Oral 200 mg/kg/day NOAEL Not carcinogenic

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

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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

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

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Material Name: Nalbuphine Hydrochloride Injection (Hospira Inc.)

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15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	Schedule 6 215-185-5
Citric acid, anhydrous	
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	201-069-1
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
Nalbuphine Hydrochloride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	245-549-9
Sodium Citrate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

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; 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.

Revision date: 09-Aug-2016

Product Stewardship Hazard Communication

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

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Material Name: Nalbuphine Hydrochloride Injection (Hospira Inc.)

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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: Naloxone Hydrochloride Injection USP

Section 1: PRODUCT AND COMPANY INFORMATION

54/1, Boodhihal village,
 Nelamangala,
 Bangalore, India-562123.
PRODUCT NAME: Naloxone Hydrochloride Injection USP 0.4 mg/mL

Section 2: HAZARD(S) IDENTIFICATION

EMERGENCY OVERVIEW	
Appearance	A clear colorless solution, free from visible extraneous matter. Filled in clear tubular glass vial plugged with rubber stopper and sealed with flip off aluminium seal.
Classification of the Substance or Mixture	
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.	
<i>Potential Health Effects: See Section 11 for more information</i>	
<i>Potential Environmental Effects: See Section 12 for more information</i>	

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS

Chemical Name	CAS Number
Naloxone Hydrochloride	51481-60-8
Sodium Chloride	7647-14-5
Hydrochloric Acid	7647-01-0
Water for injection	-



Section 4: FIRST AID MEASURES

Eye Contact	Flush eye thoroughly with water for at least 15 minutes. If irritation occurs, seek medical attention.
Swallowed	DO NOT induce vomiting. Wash out mouth with water and give plenty of water to drink. Seek medical attention.
Skin contact	Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Injection	See prescribing information.
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	
Aggravated Medical Conditions	Hypersensitivity to Naloxone Hydrochloride or to any of the other ingredients in naloxone hydrochloride injection.
Notes to Physician:	Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

Fire/Explosion Hazard	Non-combustible. Not considered a significant fire risk. Where possible, contain and collect fire-fighting water for later disposal.
Unsuitable Extinguishing Media:	No restrictions- As for primary cause of fire.
Hazchem Code	None allocated
Specific Hazards Arising from the Chemical:	
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Advice for Fire-Fighters	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.



Section 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Personal Protective Equipment and emergency procedures	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
	For personal protection see section 8.
Methods for Cleaning Up:	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Environmental Precautions:	Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
Reference to Other Sections:	Refer to Sections 8, 12 and 13 for further information.

Section 7: HANDLING AND STORAGE

Precautions for Safe Handling Hygiene Measures:	Avoid breathing vapour 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 Technical Measures:	Store as directed by product packaging.
Storage Conditions	20°C – 25°C (68°F – 77°F). Protect from light by retaining in carton until ready for use. Discard unused portion
Specific End Use	Pharmaceutical drug product



Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Pharmaceutical drug product	No exposure limits set by NOHSC or ACGIH
Engineering Controls	None under normal operating conditions.
Personal Protection	For good infection control, gloves should be worn when administering an injection.
The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information, consult your Occupational Health and Safety Adviser.	

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear colourless liquid
Odour	Odourless
Boiling Point/Melting Point	As for water (approx.)
Vapour Pressure	Not determined
Vapour Density	Not determined
Specific Gravity	As for water (approx.)
Flashpoint	Not determined
Flammability Limits	Not determined
Solubility in Water	Aqueous solution.

Section 10: STABILITY AND REACTIVITY

Reactivity:	Not known to be incompatible with other materials.
Chemical Stability:	Stable under recommended storage conditions.
Decomposition Products	Not determined
Possibility of Hazardous Reactions	
Oxidizing Properties:	None
Conditions to Avoid:	Not determined
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.



Section 11: TOXICOLOGY INFORMATION

Accidental Injection	May cause allergic reactions, nausea, palpitations, and increased blood pressure.
	Severe allergic reactions will usually occur within the first few hours of exposure. The sooner the onset of an allergic reaction, the more severe the reaction.
Eye	May cause irritation.
Swallowed	May cause allergic reactions or gastro-intestinal upset and increased blood pressure.
Skin	No adverse health effects known.
Inhaled	Not an expected route of exposure.
Chronic Health Effects	No chronic health effects known.
Carcinogen Status:	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity
Aquatic: No data available.
Terrestrial: No data available.
Persistence and Degradability: No data available.
Bio accumulative Potential: No data available.
Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

Section 13: DISPOSAL CONDITIONS

Waste Disposal:

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 waste water.



Section 14: TRANSPORTATION INFORMATION

UN Number None allocated

DG Class None allocated

Subsidiary Risk None allocated

Packing Group None allocated

Hazchem Code None allocated

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

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

Section 15: REGULATORY INFORMATION

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

Poisons Schedule Number Schedule 4 (S4) – Prescription only medicine

Section 16: OTHER INFORMATION

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 safety data sheet (SDS) 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.

This information is based on our present state of knowledge. It should not therefore be constructed as guaranteeing specific properties of the products described or their suitability for a particular application.



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

Product Identifier

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

Trade Name: Naloxone Hydrochloride Injection
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
 275 North Field Drive
 Lake Forest, Illinois 60045
 1-800-879-3477

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

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

Note:

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

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
Naloxone hydrochloride	357-08-4	206-611-0	Not Listed	0.04

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Propylparaben	94-13-3	202-307-7	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 eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
Skin Contact:	Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
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: As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture

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Material Name: Naloxone Hydrochloride Injection, USP
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Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

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

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

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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

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

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

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

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

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

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

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m ³
Austria OEL - MAKs	5 ppm
	8 mg/m ³
Belgium OEL - TWA	5 ppm
	8 mg/m ³
Bulgaria OEL - TWA	5 ppm
	8.0 mg/m ³
Cyprus OEL - TWA	5 ppm
	8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Estonia OEL - TWA	5 ppm 8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m ³
Germany (DFG) - MAK	2 ppm 3.0 mg/m ³
Greece OEL - TWA	5 ppm 7 mg/m ³
Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm 8 mg/m ³
Italy OEL - TWA	5 ppm 8 mg/m ³
Japan - OELs - Ceilings	2 ppm 3.0 mg/m ³
Latvia OEL - TWA	5 ppm 8 mg/m ³
Lithuania OEL - TWA	5 ppm 8 mg/m ³
Luxembourg OEL - TWA	5 ppm 8 mg/m ³
Malta OEL - TWA	5 ppm 8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 ppm 8 mg/m ³
Romania OEL - TWA	5 ppm 8 mg/m ³
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	5 ppm 8 mg/m ³
Spain OEL - TWA	5 ppm 7.6 mg/m ³
Switzerland OEL - TWAs	2 ppm 3.0 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³
SODIUM CHLORIDE	
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

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.

Naloxone hydrochloride

Pfizer Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

Exposure Controls

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 (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:	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:	3.0-6.5		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
HYDROCHLORIC ACID			
No data available			
SODIUM CHLORIDE			
No data available			
Methylparaben			
No data available			
Propylparaben			
No data available			
Water for Injection			
No data available			
Naloxone hydrochloride			
No data available			
Decomposition Temperature (°C):	No data available.		
Evaporation Rate (Gram/s):	No data available		
Vapor Pressure (kPa):	No data available		
Vapor Density (g/ml):	No data available		
Relative Density:	No data available		
Viscosity:	No data available		
Flammability:			
Autoignition Temperature (Solid) (°C):	No data available		

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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:	None
Conditions to Avoid:	Not determined
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

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

General Information:	The information included in this section describes the potential hazards of the individual ingredients.
Known Clinical Effects:	The most common adverse effects seen during clinical use of this drug include headache, sweating, nausea, decrease in blood pressure (hypotension), increase in blood pressure (hypertension), shortness of breath (dyspnea), increased heart rate (tachycardia), irritability, anxiety, inability to concentrate, lack of appetite.

Acute Toxicity: (Species, Route, End Point, Dose)**HYDROCHLORIC ACID**

Rat Oral LD 50 238-277 mg/kg

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³

Rat Oral LD 50 3g/kg

Mouse Oral LD 50 4g/kg

Rabbit Dermal LD 50 > 10g/kg

Naloxone hydrochloride

Rat Oral LD50 > 1000 mg/kg

Mouse Oral LD50 > 1000mg/kg

Rat Intravenous LD50 107mg/kg

Mouse Intravenous LD50 90mg/kg

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

Irritation / Sensitization: (Study Type, Species, Severity)**SODIUM CHLORIDE**

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

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11. TOXICOLOGICAL INFORMATION**Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))****Naloxone hydrochloride**

Embryo / Fetal Development	Rat	No route specified	8 times human dose	NOAEL	Not teratogenic
Embryo / Fetal Development	Mouse	No route specified	4 times human dose	NOAEL	Not Teratogenic

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

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vivo</i> Micronucleus	Rat	Negative

Naloxone hydrochloride

Bacterial Mutagenicity (Ames)	Positive
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes Positive
Mammalian Cell Mutagenicity	HGPRT Hamster Negative
<i>In Vivo</i> Chromosome Aberration	Rat Bone Marrow Negative
<i>In Vivo</i> Micronucleus	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.

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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

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

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

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	231-595-7

Propylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

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15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

Naloxone hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	206-611-0

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**

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.

Revision date: 17-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

RICHMOND OXYGEN

RichmondOxygen.com

Safety Data Sheet Oxygen, Compressed

SDS# 10001

Section 1: Product and Company Information

Richmond Oxygen
11009 Richardson Road
Ashland VA 23005

Phone: (804) 798-4243

Fax: (804) 798-2549

Emergency contact: 1-800-535-5053

Product code: Oxygen, Compressed
Part No. SDS# 10001

Section 2: Hazards Identification



DANGER

Hazard Classification:

Gases Under Pressure
Oxidizing Gas (Category 1)

Hazard Statements:

Contains gas under pressure; may explode if heated
May cause or intensify fire; oxidizer

Precautionary Statements

Prevention:

Keep reduction valves/valves and fittings free from oil and grease.
Keep and store away from clothing and combustible materials.

Response:

In case of fire: Stop leak if safe to do so.

Storage:

Protect from sunlight.
Store in well-ventilated place.

Section 3: Composition/Information on Ingredients

CAS #
7782-44-7

Chemical Substance	Chemical Family	Trade Names
OXYGEN, COMPRESSED GAS	Inorganic, gas	OXYGEN; DIOXYGEN; MOLECULAR OXYGEN; OXYGEN MOLECULE; PURE OXYGEN; UN 1072; O2

Section 4: First Aid Measures

Skin Contact	Eye Contact	Ingestion	Inhalation	Note to Physicians
None expected	None expected	Not likely route of exposure	If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.	None

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Products of Combustion	Protection of Firefighters
Non-flammable. Use extinguishing agent appropriate for the material which is burning. Use water in large quantities for fires involving oxygen.	Oxides of burning material	- Respiratory protection may be needed for frequent or heavy exposure. - None

Section 6: Accidental Release Measures

Personal Precautions	Environmental Precautions	Methods for Containment
Keep unnecessary people away, isolate hazard area and deny entry. Ventilate closed spaces before entering.	Avoid contact with combustible materials.	Stop leak if possible without personal risk.

Methods for Cleanup	Other Information
Stop leak and ventilate	None

Section 7: Handling and Storage

Handling	Storage
Store and handle in accordance with all current regulations and standards. Subject to storage regulations: U.S. OSHA 29 CFR 1910.101.	Keep separated from incompatible substances.

Section 8: Exposure Controls/Personal Protection

Exposure Guidelines
OXYGEN, COMPRESSED GAS: No occupational exposure limits established.

Engineering Controls

Handle only in fully enclosed systems.

Eye Protection	Skin Protection	Respiratory Protection
Eye protection not required, but recommended.	Protective clothing is not required.	Respiratory protection may be needed for frequent or heavy exposure.

General Hygiene considerations

- Avoid breathing vapor or mist
- Avoid contact with eyes and skin
- Wash thoroughly after handling and before eating or drinking

Section 9: Physical and Chemical Properties

Physical State	Appearance	Color	Change in Appearance	Physical Form	Odor	Taste
Gas	Clear	Colorless	N/A	Gas	Odorless	Tasteless

Flash Point	Flammability	Partition Coefficient	Autoignition Temperature	Upper Explosive Limits	Lower Explosive Limits
Not flammable	Not Available	Not Available	Nonflammable	Nonflammable	Nonflammable

Boiling Point	Freezing Point	Vapor Pressure	Vapor Density	Specific Gravity	Water Solubility	pH	Odor Threshold	Evaporation Rate	Viscosity
-297 F (-183 C)	-360 F (-218 C)	760 mmHg @ -183 C	1.1 (Air=1)	N/A	3.2% @ 25 C	N/A	Not available	N/A	0.02075 cP @ 25 C

Molecular Weight	Molecular Formula	Density	Weight per Gallon	Volatility by Volume	Volatility	Solvent Solubility
31.9988	O2	1.309 g/L @ 25 C	Not available	N/A	N/A	Soluble: Alcohol

Section 10: Stability and Reactivity

Stability	Conditions to Avoid	Incompatible Materials
Stable at normal temperatures and pressure.	Stable at normal temperatures and pressure.	Combustible materials, halo carbons, metals, bases, reducing agents, amines, metal salts, oxidizing materials, alkaline earth and alkali metals

Hazardous Decomposition Products	Possibility of Hazardous Reactions
Miscellaneous decomposition products	Will not polymerize.

Section 11: Toxicology Information

Acute Effects

Oral LD50	Dermal LD50	Inhalation
Not established	Not established	Irritation, changes in body temperature, nausea, difficulty breathing, irregular heartbeat, dizziness, disorientation, hallucinations, mood swings, pain in extremities, tremors, lung congestion, convulsions

Eye Irritation	Skin Irritation	Sensitization
No information on significant adverse effects	No information on significant adverse effects	No significant target effects reported.

Chronic Effects

Carcinogenicity	Mutagenicity	Reproductive Effects	Developmental Effects
Not known	Available	Available	No Data

Section 12: Ecological Information

Fate and Transport

Eco toxicity	Persistence / Degradability	Bioaccumulation / Accumulation	Mobility in Environment
Fish toxicity: Not available Invertebrate toxicity: Not available Algal toxicity: Not available Phyto toxicity: Not available Other toxicity: Not available	Not available	Low bioaccumulation	Not available

Section 13: Disposal Considerations

Dispose in accordance with all applicable regulations. Subject to disposal regulations: U.S. EPA 40 CFR 262.
Hazardous Waste Number(s): D001.

Section 14: Transportation Information

U.S. DOT 49 CFR 172.101

Proper Shipping Name	ID Number	Hazard Class or Division	Packing Group	Labeling Requirements	Passenger Aircraft or Railcar Quantity Limitations	Cargo Aircraft Only Quantity Limitations	Additional Shipping Description
Oxygen, compressed	UN1072	2.2	Not available	2.2; 5.1	75 kg or L	150 kg	N/A

Canadian Transportation of Dangerous Goods

Shipping Name	UN Number	Class	Packing Group / Risk Group
Oxygen, compressed	UN1072	2.2; 5.1	Not applicable

Section 15: Regulatory Information

U.S. Regulations

CERCLA Sections	SARA 355.30	SARA 355.40
Not regulated	Not regulated	Not regulated

SARA 370.21

Acute	Chronic	Fire	Reactive	Sudden Release
No	No	Yes	No	Yes

SARA 372.65

Not regulated

OSHA Process Safety

Not regulated

State Regulations

CA Proposition 65

Not regulated

Canadian Regulations

WHMIS Classification

A,C

SDS# 10001

National Inventory Status

US Inventory (TSCA)	TSCA 12b Export Notification	Canada Inventory (DSL/NDSL)
Listed on inventory.	Not listed	Not determined.

Section 16: Other Information

NFPA Rating
HEALTH=0 FIRE=0 REACTIVITY=0

0 = minimal hazard, 1 = slight hazard, 2 = moderate hazard, 3 = severe hazard, 4 = extreme hazard



SAFETY DATA SHEET

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

Product Identifier

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)

Trade Name: NITROSTAT; VERNIES
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product for the treatment of angina pectoris

Details of the Supplier of the Safety Data Sheet

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

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 4
 Acute Toxicity - Dusts and Mists: Category 4
 Specific target organ systemic toxicity (repeated exposure): Category 2

Label Elements

Signal Word: Warning
Hazard Statements: H304 - May be fatal if swallowed and enters airways
 H332 - Harmful if inhaled
 H373 - May cause damage to organs through prolonged or repeated exposure: cardiovascular

Precautionary Statements: P260 - Do not breathe dust/fume/gas/mist/vapors/spray
 P264 - Wash hands thoroughly after handling
 P270 - Do not eat, drink or smoke when using this product
 P271 - Use only outdoors or in a well-ventilated area
 P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
 P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
 P312 - Call a POISON CENTRE/doctor/physician if you feel unwell
 P501 - Dispose of contents/container in accordance with all local and national regulations

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**Other Hazards
Note:**

No data available

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	%
Nitroglycerin	55-63-0	200-240-8	Acute Tox. 2 (H300) Acute Tox. 2 (H310) STOT RE 2 (H373) Aquatic Chronic 2 (H411) Acute Tox. 2 (H330) Unst. Expl. (H200)	1.14 - 1.5
Glyceryl monostearate	31566-31-1	250-705-4	Not Listed	*
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	Not Listed	*
Calcium stearate	1592-23-0	216-472-8	Not Listed	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*

Additional Information:

* Proprietary

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

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

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

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

Skin Contact:

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

Ingestion:

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

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

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: 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: Not applicable

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. If tablets or capsules are crushed and/or broken, avoid breathing dust and 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 product

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Nitroglycerin

ACGIH Threshold Limit Value (TWA)	0.05 ppm
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route
Australia TWA	0.05 ppm
	0.46 mg/m ³
Austria OEL - MAKs	0.05 ppm
	0.5 mg/m ³
Belgium OEL - TWA	0.05 ppm
	0.47 mg/m ³
Czech Republic OEL - TWA	0.5 mg/m ³
Estonia OEL - TWA	0.03 ppm
	0.3 mg/m ³
Finland OEL - TWA	0.03 ppm
	0.3 mg/m ³
France OEL - TWA	0.1 ppm
	1 mg/m ³
Germany - TRGS 900 - TWAs	0.01 ppm
	0.094 mg/m ³
Germany (DFG) - MAK	0.01 ppm
	0.094 mg/m ³
Germany - Biological Exposure Limit:	0.5 µg/L
Greece OEL - TWA	0.2 ppm
	2 mg/m ³
Hungary OEL - TWA	0.5 mg/m ³
Ireland OEL - TWAs	0.05 ppm
	0.5 mg/m ³
Japan - OELs - Ceilings	0.05 ppm
	0.46 mg/m ³
Lithuania OEL - TWA	0.03 ppm
	0.3 mg/m ³
OSHA - Final PELs - Skin Notations:	prevent or reduce skin absorption
Poland OEL - TWA	0.5 mg/m ³
Portugal OEL - TWA	0.05 ppm
Romania OEL - TWA	0.006 ppm
	0.05 mg/m ³
Slovakia OEL - TWA	0.05 ppm
	0.47 mg/m ³
Slovenia OEL - TWA	0.05 ppm
	0.47 mg/m ³
Spain OEL - TWA	0.05 ppm
	0.5 mg/m ³
Sweden OEL - TWAs	0.03 ppm
	0.3 mg/m ³
Switzerland OEL - TWAs	0.01 ppm
	0.094 mg/m ³
UK - Biological Exposure Limit:	15 µmol/mol creatinine
Vietnam OEL - TWAs	0.5 mg/m ³

Glyceryl monostearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³
Silicon dioxide, colloidal NF	
Australia TWA	2 mg/m ³
Austria OEL - MAKs	4 mg/m ³
	0.3 mg/m ³
Czech Republic OEL - TWA	0.1 mg/m ³
	4.0 mg/m ³
Estonia OEL - TWA	2 mg/m ³
Finland OEL - TWA	5 mg/m ³
Germany - TRGS 900 - TWAs	4 mg/m ³
Germany (DFG) - MAK	4 mg/m ³
Ireland OEL - TWAs	6 mg/m ³
	2.4 mg/m ³
Latvia OEL - TWA	1 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m ³
Switzerland OEL - TWAs	4 mg/m ³
	0.3 mg/m ³
Calcium stearate	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³
Starch, pregelatinized	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Czech Republic OEL - TWA	4.0 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	4 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL - TWAs	3 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 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.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:	Tablet	Color:	White
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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

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

Calcium stearate

No data available

Glyceryl monostearate

No data available

Lactose NF, monohydrate

No data available

Nitroglycerin

No data available

Silicon dioxide, colloidal NF

No data available

Starch, pregelatinized

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C):

No data available

Flammability (Solids):

No data available

Flash Point (Liquid) (°C):

No data available

Upper Explosive Limits (Liquid) (% by Vol.):

No data available

Lower Explosive Limits (Liquid) (% by Vol.):

No data available. The active ingredient in this formulation is highly explosive. However, based on the amount of active ingredient contained in this product it is not expected to pose an explosion risk.

Polymerization:

Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

SAFETY DATA SHEET

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)
Revision date: 28-Mar-2016

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10. STABILITY AND REACTIVITY

Oxidizing Properties:	No data available
Conditions to Avoid:	Avoid direct sunlight, conditions that might generate heat, and sources of ignition.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	None known

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. Chest pain, acute myocardial infarction, and sudden death have occurred during temporary withdrawal of organic nitrates from industrial workers exposed for long periods of time.
Known Clinical Effects:	Headache, which may be severe and persistent, may occur immediately after use. Vertigo, dizziness, weakness, palpitation, and other manifestations of postural hypotension may develop occasionally. Flushing, drug rash, and exfoliative dermatitis have been reported in patients receiving nitrate therapy.

Acute Toxicity: (Species, Route, End Point, Dose)**Glyceryl monostearate**

Mouse IP LD50 200 mg/kg

Nitroglycerin

Rat Oral LD50 105 mg/kg
Mouse Oral LD50 115mg/kg
Rabbit Dermal LD50 > 280mg/kg
Rat Dermal LD50 > 29mg/kg
Rat IV LD50 23.2mg/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.

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**Nitroglycerin**

Fertility and Embryonic Development Rat Oral 434 mg/kg/day NOAEL Negative
Embryo / Fetal Development Rabbit Oral 240 mg/kg/day NOAEL Not Teratogenic

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

Bacterial Mutagenicity (Ames) *Salmonella* Positive
In Vivo Dominant Lethal Assay Rat Negative
In Vitro Cytogenetics Rat Negative

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

2 Year(s) Rat Oral 434 mg/kg/day LOAEL Liver, Male reproductive system
2 Year(s) Mouse Oral 1058 mg/kg/day NOAEL Not carcinogenic

SAFETY DATA SHEET

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)
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11. TOXICOLOGICAL INFORMATION

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

Silicon dioxide, colloidal NF
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Based on the concentration of the active ingredient in the formulation, No harmful effects to aquatic organisms are expected.

Toxicity:

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

Nitroglycerin

Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours 1.91 mg/L
Midge LC50 48 Hours 20 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.

Nitroglycerin
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.

SAFETY DATA SHEET

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15. REGULATORY INFORMATION

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

Nitroglycerin

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	10 lb
California Proposition 65	4.54 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 3
	Schedule 4
	200-240-8

Glyceryl monostearate

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	250-705-4

Silicon dioxide, colloidal NF

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	231-545-4

Calcium 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	216-472-8

Starch, pregelatinized

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	232-679-6

Lactose NF, monohydrate

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

SAFETY DATA SHEET

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)
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15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	Not Listed

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

Explosives-Unstable explosives; H200 - Unstable explosive
 Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed
 Acute toxicity, dermal-Cat.2; H310 - Fatal in contact with skin
 Acute toxicity, inhalation-Cat.2; H330 - Fatal if inhaled
 Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
 Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.

Revision date: 28-Mar-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



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 Fax: (845) 365-8201

Reorder # 1108, 1201-1202-1207; HS-1125637

Reviewed on 1/7/15

Safety Data Sheet

SECTION 1. Product and Company Identification

Product/Trade Name: Povidone iodine pads
 Povidone iodine swabsticks
 Manufacturer's Name: Dynarex Corporation
 Manufacturer's Address: 10 Glenshaw Street
 Orangeburg, NY 10962
 Emergency or Information Phone No.: 888-DYNAREX or 845-365-8201
 At other times, contact the local Poison Control Center

SECTION 2. Hazards Identification

GHS Label elements, including precautionary statements

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

Appearance: Dark brown liquid absorbed into white pad / swab.

Physical State: Thin liquid absorbed onto pad / swab.

Odor: Faint characteristic

Precautionary Statements - Prevention None

Precautionary Statements - Response None

Precautionary Statements - Storage None

Precautionary Statements - Disposal None

Hazards not otherwise classified (HNOC) Not applicable

Unknown Toxicity - 11% of the mixture consists of ingredient(s) of unknown toxicity

Other information - Harmful to aquatic life with long lasting effects.

Interactions with Other Chemicals - Incompatible with strong alkalis.

SECTION 3. Composition/Information on Ingredients

INGREDIENTS	CAS NUMBER	WT. %	ACGIH-TLV
Povidone Iodine	25655-41-8	10	None Established
Nonoxynol-9	26571-11-9	2	None Established
Water	7732-18-5	88	None Established



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SECTION 4. First-Aid Measures

Skin Contact:	Discontinue if rash or irritation is noted.
Eye Contact:	Flush with cool water for 15 minutes. If eye irritation persists: Get medical advice/attention.
Inhalation:	Remove to fresh air. If symptoms persist, call a doctor
Ingestion:	Do not induce vomiting. Get medical attention.
Target Organs:	N/A

SECTION 5. Fire-Fighting Measures

Extinguishing Media:	Any
Special Fire-fighting Procedures:	None
Unusual Fire and Explosion Hazards:	May emit toxic fumes of iodine in a fire.

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

Harsh iodine fumes may be emitted if product is heated to temperatures greater than 80°C.

Hazardous Combustion Products

Carbon oxides.

SECTION 6. Accidental Release Measures

Use absorbent material and dispose per local regulations.

SECTION 7. Handling and Storage

Avoid storing at extreme temperatures.

Store under dry conditions.

Executive Headquarters: Ten Glenshaw Street, Orangeburg, NY 10962



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SECTION 8. Exposure Controls/Personal Protection

Exposure Guidelines

Chemical Name

Iodine
7553-56-2

ACGIH TLV

TWA: 0.01 ppm
(Inhalable fraction and vapor)
STEL: 0.1 ppm
(Aerosol and vapor)

OSHA PEL

TWA-Ceiling: 0.1 ppm

NIOSH IDLH

IDLH: 2 ppm
TWA-Ceiling: 0.1 ppm

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value OSH

Respiration:	None
Ventilation:	None
Protective Gloves:	If handling liquid
Eye Protection:	If splashing is a hazard
Hygienic Practices:	Good housekeeping practices should be followed.
Other:	Wear apron to protect clothing.

SECTION 9. Physical and Chemical Properties

Color/Appearance:	Applicator saturated with dark reddish brown liquid
Odor:	Faint Iodine
Boiling Point:	N/A
Vapor Density:	N/A
Evaporation Rate:	N/A
Solubility in Water:	Soluble
Specific Gravity (H ₂ O=1):	N/A

SECTION 10. Stability and Reactivity

Stability:	Stable
Conditions to avoid:	None known
Incompatibility:	Alkalis and reducing agents
Hazardous Decomposition of By-products:	Emits iodine vapors at high temperatures



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Polymerization: Will not occur

SECTION 11. Toxicological Information

Skin:	May cause irritation
Eyes:	May be irritating
Inhalation:	None
Ingestion:	Harmful
Ecotoxicity	Harmful to aquatic life with long lasting effects.

SECTION 12. Ecological Information

Ecotoxicity Harmful to aquatic life with long lasting effects.
 Environmental effects Not available
 Aquatic toxicity Not available
 Persistence / degradability Not available
 Bioaccumulation / accumulation Not available
 Partition coefficient Not available
 Mobility in environmental media Not available
 Chemical fate information Not available
 Other adverse effects Not available

SECTION 13. Disposal Considerations

Follow local, state and federal regulations.

SECTION 14. Transport Information

DOT Shipping Name:	Not regulated
TDG	Not regulated
ICAO	Not regulated
IATA	Not regulated
IMDG/IMO	Not regulated



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SECTION 15. Regulatory Information

Canadian federal regulations This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

NPN 00489948 - Pad/ NPN 00489964 - Swabstick

US Federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200 due to the presence of listed sensitizers. All components are on the U.S. EPA TSCA Inventory List.

Occupational Safety and Health Administration (OSHA)

29 CFR 1910.1200 hazardous chemical

Yes

CERCLA (Superfund) reportable quantity

Sodium hydroxide: 1000.0000

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

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

Section 302 extremely hazardous substance No

Section 311 hazardous chemical Yes

Clean Air Act (CAA) Not available

Clean Water Act (CWA) Not available

Safe Drinking Water Act (SDWA) Not available

Drug Enforcement Agency (DEA) Not available

Food and Drug Administration

(FDA) Not available

WHMIS classification Exempt - Registered product - (NHP see above)

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



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SECTION 16. Other information

Abbreviations

N/A: Denotes no applicable information found or available
 CAS#: Chemical Abstracts Service Number
 ACGIH: American Conference of Governmental Industrial Hygienists
 OSHA: Occupational Safety and Health Administration
 TLV: Threshold Limit Value
 PEL: Permissible Exposure Limit
 STEL: Short Term Exposure Limit
 NTP: National Toxicology Program
 IARC: International Agency for Research on Cancer
 EU: European Union
 R: Risk
 S: Safety

Disclaimer: This Safety Data Sheet, which takes into consideration the requirements of Directive 76/768/EC and subsequent amendments and Directive 1999/45/EC plus subsequent amendments, has been prepared in accordance with Directive (EC) 1907/2006. It is believed to be correct and corresponds to the latest scientific/technical knowledge but all data, instructions, recommendations and/or suggestions are made without guarantee. No warranty, expressed or implied, is made and Dynarex Corp. assumes no legal responsibility or liability resulting from its use.



SAFETY DATA SHEET



1. Product and Company Identification

Product identifier	Prevantics® Swab, Swabstick and Maxi Swabstick	SDS No.0001
Other means of identification	Not available	
Recommended use	For the preparation of the patient's skin prior to an injection/surgery.	
Recommended restrictions	For Professional and Hospital Use	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	Professional Disposables International, Inc.	
Address	Two Nice-Pak Park Orangeburg, NY 10962-1376	
Telephone	Phone (USA)	1-845-365-1700 (M-F 9am - 5pm)
E-mail	pdihc.com	
Emergency phone number	1-800-999-6423	

2. Hazards Identification

Physical hazards	Flammable solids	Category 1
Health hazards	Serious eye damage/eye irritation	Category 1
Environmental hazards	Not determined.	
OSHA defined hazards	None additional.	
Label elements		
Signal word	Warning	
Hazard statement	Flammable solid. Causes serious eye damage.	
Precautionary statement		
Prevention	Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use only in a well-ventilated area. Wear gloves/eye protection.	
Response	If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. In case of fire: Use appropriate media to extinguish.	
Storage	Store in a well-ventilated place. Keep container tightly closed.	
Disposal	Dispose of waste and residues in accordance with local authority requirements.	
Hazard(s) not otherwise classified (HNOC)	None known.	
Supplemental information	Not applicable.	

3. Composition/Information on Ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Isopropanol		67-63-0	70(v/v)
Chlorhexidine gluconate		18472-51-0	3.15(w/v)

Composition comments Active ingredient(s) are listed above.

4. First Aid Measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	In case of skin irritation, discontinue use of product. Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.
Ingestion	If swallowed, get medical help or contact a Poison Control Center immediately. Immediately rinse mouth out with water. Do not induce vomiting. If vomiting occurs naturally, have victim lean forward to reduce risk of aspiration. Never give anything by mouth if victim is unconscious, or is convulsing.
Most important symptoms/effects, acute and delayed	Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

5. Fire Fighting Measures

Suitable extinguishing media	Alcohol resistant foam. Carbon dioxide (CO ₂). Dry chemical.
Unsuitable extinguishing media	Not available.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA. Structural firefighters protective clothing will only provide limited protection.
Fire-fighting equipment/instructions	In case of fire and/or explosion do not breathe fumes. In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk. Cool containers exposed to flames with water until well after the fire is out. In the event of fire and/or explosion do not breathe fumes.
General fire hazards	Flammable solid.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Wear appropriate protective equipment and clothing during clean-up. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). For waste disposal, see Section 13 of the SDS. Never return spills in original containers for re-use. Collect and dispose of spillage as indicated in section 13 of the SDS.
Environmental precautions	Avoid discharge into water courses.

7. Handling and Storage

Precautions for safe handling	WARNING Flammable, keep away from fire or flame. For external use only. Do not use with electrocautery procedures. Do not use under occlusive patches. Use according to package label instructions. Do not use on patients with known allergies to chlorhexidine gluconate or isopropyl alcohol. Do not use for lumbar puncture or in contact with the meninges. Do not use on open wounds or as a general skin cleanser. Discard after single use. Wear appropriate personal protective equipment. Do not get this material in contact with eyes. Avoid prolonged exposure. Provide adequate ventilation. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Observe good industrial hygiene practices. Use care in handling/storage.

Conditions for safe storage, including any incompatibilities

Store between 68°F and 77°F (20°C - 25°C).
Do not store at temperatures above 40°C (104°F).
Keep from freezing.
For hospital and professional use only.

Keep away from heat, sparks and open flame.
Store in a cool, dry place out of direct sunlight.
Store in a well-ventilated place.
Store in original tightly closed container.
Store away from incompatible materials (see Section 10 of the SDS).
Keep out of reach of children.

8. Exposure Controls/Personal Protection

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

Components	Type	Value
Isopropanol (CAS 67-63-0)	PEL	980 mg/m3 400 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
Isopropanol (CAS 67-63-0)	STEL	400 ppm
	TWA	200 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Isopropanol (CAS 67-63-0)	STEL	1225 mg/m3 500 ppm
	TWA	980 mg/m3 400 ppm

Biological limit values**ACGIH Biological Exposure Indices**

Components	Value	Determinant	Specimen	Sampling Time
Isopropanol (CAS 67-63-0)	40 mg/l	Acetone	Urine	*

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

Exposure guidelines

See above

Appropriate engineering controls

Ensure adequate ventilation. Provide eyewash station.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear gear as deemed necessary. Follow label directions.

Skin protection**Hand protection**

Wear as deemed necessary, follow label directions.

Other

Follow label directions carefully.

Respiratory protection

Wear positive pressure self-contained breathing apparatus (SCBA).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the product. When using do not smoke. When using do not eat or drink.

9. Physical and Chemical Properties

Appearance	Liquid Saturated Swab and Swabstick
Physical state	Solid.
Form	Solid containing liquid.
Color	Clear colorless
Odor	Mild alcohol.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.

Pour point	Not available.
Specific gravity	Not available.
Partition coefficient (n-octanol/water)	Not available.
Flash point	78.0 °F (25.6 °C) Tag Closed Cup
Evaporation rate	Not available.
Flammability (solid, gas)	Flammable solid.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and Reactivity

Reactivity	This product may react with strong oxidizing agents.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Chemical stability	Material is stable under normal conditions.
Conditions to avoid	Heat, flames and sparks. Avoid temperatures exceeding the flash point. Do not mix with other chemicals. Do not use hypochlorite bleach on fabrics exposed to Chlorhexidine Gluconate.
Incompatible materials	Strong oxidizing agents. Anionic surfactants. Soaps. Hypochlorite bleach
Hazardous decomposition products	May include and are not limited to: Oxides of carbon. Oxides of nitrogen. Hydrogen chloride. Ammonia.

11. Toxicological Information

Information on likely routes of exposure

Ingestion	Not applicable under normal conditions of use.
Inhalation	Vapors have a narcotic effect and may cause headache, fatigue, dizziness and nausea. Health injuries are not known or expected under normal use.
Skin contact	Not expected to be a primary skin irritant.
Eye contact	Causes irritation.
Symptoms related to the physical, chemical and toxicological characteristics	Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result.

Information on toxicological effects

Acute toxicity	Narcotic effects.

Components	Species	Test Results
Chlorhexidine gluconate (CAS 18472-51-0)		
Acute		
LC50	Not available	
Oral LD50	Mouse	1260 mg/kg
	Rat	2000 mg/kg

Components	Species	Test Results
Isopropanol (CAS 67-63-0)		
Acute		
Dermal		
LD50	Rabbit	12800 mg/kg
Inhalation		
LC50	Rat	16970 mg/l/4h
Oral		
LD50	Dog	4797 mg/kg
	Mouse	3600 mg/kg
	Rabbit	5030 mg/kg
	Rat	4396 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Exposure minutes	Not available.	
Erythema value	Not available.	
Oedema value	Not available.	
Serious eye damage/eye irritation	Causes irritation.	
Corneal opacity value	Not available.	
Iris lesion value	Not available.	
Conjunctival reddening value	Not available.	
Conjunctival oedema value	Not available.	
Recover days	Not available.	
Respiratory or skin sensitization		
Respiratory sensitization	Not available.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Germ cell mutagenicity	The finished product is not expected to have chronic health effects.	
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not listed.		
Reproductive toxicity	The finished product is not expected to have chronic health effects.	
Specific target organ toxicity - single exposure	Narcotic effects.	
Specific target organ toxicity - repeated exposure	Not classified.	
Aspiration hazard	Not classified.	
Chronic effects	Prolonged inhalation may be harmful.	
Further information	Not available.	

12. Ecological Information

Ecotoxicity	See below		
Components		Species	Test Results
Isopropanol (CAS 67-63-0)			
Algae	IC50	Algae	1000 mg/L, 72 Hours
Crustacea	EC50	Daphnia	13299 mg/L, 48 Hours
Aquatic			
Fish	LC50	Bluegill (Lepomis macrochirus)	> 1400 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of this product.		
Bioaccumulative potential	No data available.		
Partition coefficient n-octanol / water (log Kow)			
Isopropanol		0.05	
Mobility in soil	No data available.		
Mobility in general	Not available.		

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal Considerations

Disposal instructions Follow container label directions carefully. Do not reuse swab/swabstick. Dispose of used swab/swabstick in trash. Do not flush in toilet. Do not reuse empty container. Wrap container and put in trash collection. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code Dispose in accordance with all applicable regulations.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport Information

U.S. Department of Transportation (DOT)

Not regulated as dangerous goods.

Special Provision 47

15. Regulatory Information

US federal regulations This product is regulated by the US FDA as a drug product.

FDA Registration No: 021524

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Isopropanol (CAS 67-63-0)

Listed.

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

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

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

SARA 302 Extremely hazardous substance

No

SARA 311/312 Hazardous chemical

No

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
Isopropanol	67-63-0	70(v/v)

Other federal regulations

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

Not regulated.

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

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

Food and Drug Administration (FDA)

Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

US - California Hazardous Substances (Director's): Listed substance

Isopropanol (CAS 67-63-0)

Listed.

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

Not listed.

US - Illinois Chemical Safety Act: Listed substance

Isopropanol (CAS 67-63-0) Listed.

US - Louisiana Spill Reporting: Listed substance

Isopropanol (CAS 67-63-0) Listed.

US - Minnesota Haz Subs: Listed substance

Isopropanol (CAS 67-63-0) Listed.

US - New Jersey RTK - Substances: Listed substance

Isopropanol (CAS 67-63-0) Listed.

US. Massachusetts RTK - Substance List

Isopropanol (CAS 67-63-0) Listed.

US. Pennsylvania RTK - Hazardous Substances

Isopropanol (CAS 67-63-0) Listed.

US. Rhode Island RTK

Isopropanol (CAS 67-63-0) Listed.

Country(s) or region

United States & Puerto Rico

Inventory name

Toxic Substances Control Act (TSCA) Inventory

On inventory (yes/no)*

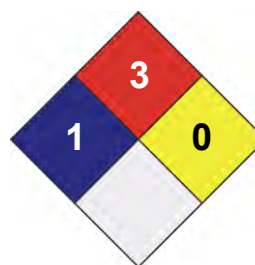
Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

16. Other Information

LEGEND	
Severe	4
Serious	3
Moderate	2
Slight	1
Minimal	0

HEALTH	/ 1
FLAMMABILITY	3
PHYSICAL HAZARD	0
PERSONAL PROTECTION	X

**Disclaimer**

The information in the sheet was written based on the best knowledge and experience currently available. Information contained herein was obtained from sources considered technically accurate and reliable. While every effort has been made to ensure full disclosure of product hazards, in some cases data is not available and is so stated. Since conditions of actual product use are beyond control of the supplier, it is assumed that users of this material have been fully trained according to the requirements of all applicable legislation and regulatory instruments. No warranty, expressed or implied, is made and supplier will not be liable for any losses, injuries or consequential damages which may result from the use of or reliance on any information contained in this document.

Issue date

08-October-2014

Further information

For any questions surrounding this SDS, please contact the supplier/manufacturer listed on the first page of the document.

DO NOT USE IF PACKAGE IS OPENED.

Registration Numbers:

B10800- NDC 10819-1080-1

B11400- NDC 10819-1080-2

S40750- NDC 10819-4075-1

S32450- NDC 10819-4075-2

S42850- NDC 10819-4075-5

S41950- NDC 10819-4075-4

S27350- NDC 10819-4075-3

Other information

This Safety Data Sheet was prepared to comply with the current OSHA Hazard Communication Standard (HCS) adoption of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

Prepared by

Dell Tech Laboratories, Ltd. Phone: (519) 858-5021

Conforms to HazCom 2012/United States

SAFETY DATA SHEET

Promethazine HCl Injection, USP**hikma.**

Section 1. Identification

GHS product identifier	: Promethazine HCl Injection, USP
Synonyms	: Phenergan® (Promethazine HCl) Injection
Product code	: Not available.
Chemical family	: Anticholinergic Agent. Antihistaminic Agent. Antiemetic. Sedative.
Product type	: Regulated prescription drug.
Container information	: 1 mL vials or ampuls.
Identified uses	: Pharmaceutical.
Supplier's details	: Hikma Pharmaceuticals USA Inc. 246 Industrial Way West Eatontown, New Jersey (NJ) 07724
Emergency telephone number (with hours of operation)	: CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887 24/7

Section 2. Hazards identification

OSHA/HCS status	: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Classification of the substance or mixture	: SKIN SENSITIZATION - Category 1 AQUATIC HAZARD (LONG-TERM) - Category 3

GHS label elements

Hazard pictograms**Signal word**

: Warning

Hazard statements: May cause an allergic skin reaction.
Harmful to aquatic life with long lasting effects.

Precautionary statements

General

: Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.

Prevention

: Wear protective gloves. Avoid release to the environment. Avoid breathing vapor. Contaminated work clothing should not be allowed out of the workplace.

Response

: IF ON SKIN: Wash with plenty of soap and water. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention.

Storage

: Not applicable.

hikma.**Promethazine HCl Injection, USP****Section 2. Hazards identification**

Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Other means of identification : Phenergan® (Promethazine HCl) Injection

CAS number/other identifiers

CAS number : Not applicable.

Product code : Not available.

Ingredient name	%	CAS number
Water	60 - 100	7732-18-5
Promethazine hydrochloride	1 - 5	58-33-3
Phenol	0.1 - 1	108-95-2
Disodium dihydrogen ethylenediaminetetraacetate	0 - 0.1	139-33-3
Sodium metabisulphite	0 - 0.1	7681-57-4
Calcium chloride	0 - 0.1	10043-52-4

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

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

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

Section 4. First aid measures**Description of necessary first aid measures**

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Section 4. First aid measures

- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed**Potential acute health effects**

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

Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No known significant effects or critical hazards.

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

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures**Extinguishing media**

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

- Specific hazards arising from the chemical** : This material is harmful to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

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

Section 5. Fire-fighting measures

- Special protective actions for fire-fighters** : No special measures are required.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures**Personal precautions, protective equipment and emergency procedures**

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

Methods and materials for containment and cleaning up

- Spill** : Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage**Precautions for safe handling**

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. Avoid release to the environment. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal 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.



Promethazine HCl Injection, USP

Section 14. Transport information

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

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 : Not listed
(b) Hazardous Air
Pollutants (HAPs)

Clean Air Act Section 602 : Not listed
Class I Substances

Clean Air Act Section 602 : Not listed
Class II Substances

DEA List I Chemicals : Not listed
(Precursor Chemicals)

DEA List II Chemicals : Not listed
(Essential Chemicals)

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

1. Identification

Product identifier	RED Z®
Other means of identification	Not available.
Recommended use	Not available.
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	
Manufacturer:	Safetec of America, Inc. 887 Kensington Avenue Buffalo, NY 14215 1-716-895-1822
Company Telephone:	1-716-895-1822
E-mail Address:	www.safetec.com
Emergency Telephone:	1-800-255-3924
Supplier	Refer to Manufacturer

2. Hazard(s) identification

Physical hazards	This mixture does not meet the classification criteria according to OSHA HazCom 2012.
Health hazards	This mixture does not meet the classification criteria according to OSHA HazCom 2012.
Environmental hazards	This mixture does not meet the classification criteria according to OSHA HazCom 2012.
OSHA defined hazards	This mixture does not meet the classification criteria according to OSHA HazCom 2012.

Label elements

Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	None required according to OSHA Hazcom 2012.
Response	None required according to OSHA Hazcom 2012.
Storage	None required according to OSHA Hazcom 2012.
Disposal	None required according to OSHA Hazcom 2012.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Superabsorbent Polymer		9033-79-8	> 97
Sodium dichloro-s-triazinetriene	SODIUM DICHLOROISOCYANURATE	2893-78-9	0.25

4. First-aid measures

Inhalation	If symptoms develop move victim to fresh air. Get medical attention if symptoms persist.
Skin contact	Wash off with warm water and soap. Get medical attention if symptoms occur.
Eye contact	Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.
Ingestion	Seek medical advice.
Most important symptoms/effects, acute and delayed	May be mildly irritating to skin, eyes and respiratory system.

Indication of immediate medical attention and special treatment needed Treat symptomatically.

5. Fire-fighting measures

Suitable extinguishing media Water. Water Spray or Fog. Dry chemicals. Foam. Carbon dioxide (CO₂).
Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical Thermal decomposition or combustion may liberate toxic gases or fumes.
Special protective equipment and precautions for firefighters None known.
Fire fighting equipment/instructions Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
General fire hazards No unusual fire or explosion hazards noted.
Hazardous combustion products Carbon oxides. Nitrogen oxides (NO_x).

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up Avoid dust formation. Sweep up or vacuum up spillage and collect in suitable container for disposal. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. After dust removal, flush contaminated area thoroughly with water.
Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Avoid dust formation. Use only with adequate ventilation. Wash thoroughly after handling.
Conditions for safe storage, including any incompatibilities Keep container tightly closed. Keep cool. Store away from incompatible materials.

8. Exposure controls/personal protection

Occupational exposure limits No exposure limits noted for ingredient(s).
Biological limit values No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls Ensure adequate ventilation, especially in confined areas.
Individual protection measures, such as personal protective equipment
Eye/face protection Wear safety glasses with side shields (or goggles).
Skin protection
Hand protection Chemical resistant gloves recommended.
Other Wear chemical-resistant gloves, footwear, and protective clothing appropriate for the risk of exposure. Contact health or safety professional or manufacturer for specific information.
Respiratory protection Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards Not available.
General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance Granular powder.
Physical state Solid.
Form Powder.
Color Off-white.
Odor Slight chlorine.

Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Slight.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	High humidity. High temperatures.
Incompatible materials	Strong reducing agents.
Hazardous decomposition products	Carbon oxides. Nitrogen oxides (NOx).

11. Toxicological information

Information on likely routes of exposure

Inhalation	Inhalation of dusts may cause respiratory irritation.
Skin contact	May cause mild skin irritation.
Eye contact	May cause mild eye irritation.
Ingestion	No harmful effects expected in amounts likely to be ingested by accident.
Most important symptoms/effects, acute and delayed	May be mildly irritating to skin, eyes and respiratory system.

Information on toxicological effects

Acute toxicity	No adverse effects are expected.
Skin corrosion/irritation	May cause mild skin irritation.
Serious eye damage/eye irritation	May cause mild eye irritation.
Respiratory or skin sensitization	
Respiratory sensitization	This product is not expected to cause respiratory sensitization.
Skin sensitizer	This product is not expected to cause skin sensitization.

Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity	This product is not expected to cause reproductive effects.
Specific target organ toxicity - single exposure	Not classified as a specific target organ toxicity -single exposure.
Specific target organ toxicity - repeated exposure	Not classified as a specific target organ toxicity -repeated exposure.
Aspiration toxicity	Not expected to be an aspiration hazard.

12. Ecological information

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

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
All components are on the U.S. EPA TSCA Inventory List.

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

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

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations**US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

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

Not listed.

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

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

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

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

Issue date	02-23-2015
Version #	01

Disclaimer

Prepared by: ICC The Compliance Center Inc. 1-888-442-9628
<http://www.thecompliancecenter.com>

Disclaimer

This Safety Data Sheet was prepared by ICC The Compliance Center Inc. using information provided by / obtained from and CCOHS' Web Information Service. The information in the Safety Data Sheet is offered for your consideration and guidance when exposed to this product. ICC The Compliance Center Inc. and expressly disclaim all expressed or implied warranties and assume no responsibilities for the accuracy or completeness of the data contained herein. The data in this SDS does not apply to use with any other product or in any other process.

This Safety Data Sheet may not be changed, or altered in any way without the expressed knowledge and permission of ICC The Compliance Center Inc. and

Revision Information

Product and Company Identification: Product and Company Identification
 Composition / Information on Ingredients: Ingredients
 Physical & Chemical Properties: Multiple Properties
 Regulatory Information: United States
 GHS: Classification

Bibliography

ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices (2014)
 Canadian Centre for Occupational Health and Safety, CCInfoWeb Databases, 2014
 (Chempendium, RTECs, HSDB, INCHEM)
 European Chemicals Bureau, Existing Chemicals Work Area, EINECS Information System, 2014.
 Material Safety Data Sheet from manufacturer.
 OECD - The Global Portal to Information on Chemical Substances - eChemPortal, 2014.

McKESSON

SDS DATE: 11.11.15

***** SAFETY DATA SHEET*******SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**

PRODUCT NAME: SELECT® Povidone Iodine, USP Swabsticks
REORDER #: 986 (1's), 987 (3's)

MANUFACTURED FOR: McKesson Medical Surgical, Inc.
 9954 Mayland Drive
 Richmond, VA 23233

INFORMATION LINE: 1-800-777-4908

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

PRODUCT DESCRIPTION: N/A

SECTION 2: COMPOSITION/INFORMATION OF INGREDIENTS

<u>INGREDIENT</u>	<u>CAS NO.</u>	<u>%</u>	<u>EXPOSURE LIMITS</u>
Povidone Iodine Powder	25655-41-8	4.9%	N/A
Purified Water	7732-18-5	95.1%	N/A

SECTION 2 NOTES: N/A

SECTION 3: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: Skin contact, Ingestion, Eye contact, Inhalation

POTENTIAL HEALTH EFFECTS

EYES: Irritation to eyes if contact occurs

SKIN: Irritation to skin if contact occurs

INGESTION: Harmful if swallowed

INHALATION: Harmful if inhaled

ACUTE HEALTH HAZARDS: N/A

CHRONIC HEALTH HAZARDS: N/A

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: N/A

CARCINOGENICITY

OSHA: N/A

ACGIH: N/A

NTP: N/A

IARC: N/A

OTHER: N/A

SECTION 3 NOTES: N/A

SECTION 4: FIRST-AID MEASURES

EYES: Immediately flood the eye with plenty of water for at least 15 minutes, holding the eyes open. Obtain medical attention if soreness or redness persists.

SKIN: Immediately flood the skin with large quantities of water. Remove contaminated clothing and continue washing. Obtain medical attention if blistering occurs or redness persists.

INGESTION: Do not induce vomiting. Have victim drink 1—3 glasses of water to dilute stomach contents. If there is difficulty in breathing, give oxygen. Obtain medical attention immediately.

INHALATION: Remove from exposure. If there is difficulty in breathing, give oxygen. Obtain medical attention immediately.

MCKESSON

SDS DATE: 11.11.15

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: N/A

SECTION 4 NOTES: N/A

SECTION 5: FIRE-FIGHTING MEASURES

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

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

AUTOIGNITION TEMPERATURE: 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
PROTECTION: N/A		

EXTINGUISHING MEDIA: Use dry chemical, foam or carbon dioxide. Be aware of the possibility of re-ignition. Keep containers and surrounding cool with waterspray.

SPECIAL FIRE FIGHTING PROCEDURES: Wear full protective clothing and self-contained breathing apparatus.

UNUSUAL FIRE AND EXPLOSION HAZARDS: N/A

HAZARDOUS DECOMPOSITION PRODUCTS: N/A

SECTION 5 NOTES: Non-flammable liquid.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: N/A

SECTION 6 NOTES: N/A

SECTION 7: HANDLING AND STORAGE

HANDLING: N/A

STORAGE: Store in the sealed containers. Storage areas should be cool, dry, and well-ventilated away from incompatible materials.

OTHER PRECAUTIONS: N/A

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

VENTILATION: N/A

RESPIRATORY PROTECTION: N/A

EYE PROTECTION: N/A

SKIN PROTECTION: N/A

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

MCKESSON

SDS DATE: 11.11.15

WORK HYGIENIC PRACTICES: N/A

EXPOSURE GUIDELINES: N/A

SECTION 8 NOTES: N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: N/A

PHYSICAL STATE: N/A

pH AS SUPPLIED: N/A

pH (Other: N/A

BOILING POINT: N/A

MELTING POINT: N/A

FREEZING POINT: N/A

VAPOR PRESSURE (mmHg): N/A

@ N/A

VAPOR DENSITY (AIR = 1): N/A

@ N/A

SPECIFIC GRAVITY (H₂O = 1): N/A

@ N/A

EVAPORATION RATE: N/A

BASIS (≈1): N/A

SOLUBILITY IN WATER: N/A

PERCENT SOLIDS BY WEIGHT: N/A

PERCENT VOLATILE: N/A

BY WT/ N/A BY VOL @ N/A

VOLATILE ORGANIC COMPOUNDS (VOC): N/A

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

MOLECULAR WEIGHT: N/A

VISCOSITY: N/A

@ N/A

SECTION 9 NOTES: N/A

SECTION 10: STABILITY AND REACTIVITY

STABLE

UNSTABLE

STABILITY: X

CONDITIONS TO AVOID (STABILITY): N/A

INCOMPATIBILITY (MATERIAL TO AVOID): N/A

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: N/A

HAZARDOUS POLYMERIZATION: N/A

CONDITIONS TO AVOID (POLYMERIZATION): N/A

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SDS DATE: 11.11.15

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: N/A

SECTION 11 NOTES: N/A

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: N/A

SECTION 12 NOTES: N/A

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD:

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION

PROPER SHIPPING NAME: N/A

HAZARD CLASS: N/A

DOT SHIPPING ID NUMBER: N/A

DOT PACKING GROUP: N/A

DOT LABEL STATEMENT: N/A

WATER TRANSPORTATION

PROPER SHIPPING NAME: N/A

HAZARD CLASS: N/A

ID NUMBER: N/A

PACKING GROUP: N/A

LABEL STATEMENTS: N/A

AIR TRANSPORTATION

PROPER SHIPPING NAME: N/A

HAZARD CLASS: N/A

ID NUMBER: N/A

PACKING GROUP: N/A

LABEL STATEMENTS: N/A

SECTION 14 NOTES: N/A

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TSCA (TOXIC SUBSTANCE CONTROL ACT): N/A

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

311/312 HAZARD CATEGORIES: N/A

313 REPORTABLE INGREDIENTS: N/A

STATE REGULATIONS: N/A

INTERNATIONAL REGULATIONS: N/A

McKESSON**SDS DATE:** 11.11.15**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.



SAFETY DATA SHEET

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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

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification 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	*

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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.

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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/m³

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.

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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		

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Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

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

General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: 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.

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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

SAFETY DATA SHEET

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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

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

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

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

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

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15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
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.

SAFETY DATA SHEET

Material Name: Silvadene Cream (Silver sulfadiazine)
Revision date: 07-Nov-2017

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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

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End of Safety Data Sheet



Material Safety Data Sheet
Silver Sulfadiazine 1% Cream

Creation Date: July 9, 2009
Revision Date: October 28, 2010

1. Substance/preparation and Company identification	
<u>Company</u> Dr. Reddy's Laboratories 8800 Line Avenue Shreveport, Louisiana 71106, USA	<u>24 Hour Emergency Response Information</u> CHEMTREC: 1-800-424-9300

2. Composition information on the Ingredients		
CAS Number	Content (W/W)	Chemical Name
7732-18-5	60-80%	Water
8009-03-8	5-15%	Petrolatum
9004-99-3	3-7%	Ethoxylated stearic acid
112-92-5	3-7%	1-Octadecanol
36653-82-4	0-7%	Hexadecan-1-ol
57-55-6	1-5%	Propylene glycol
110-27-0	1-5%	Tetradecanoic acid, 1-methylethyl ester
22199-08-2	1%	Silver sulfadiazine

3. Hazard Identification
<u>Emergency Overview</u> Caution: May cause eye, skin, and respiratory tract irritation. Ingestion: May cause gastric disturbances. May cause sensitization by skin contact. Avoid contact with the skin, eyes, and clothing.
<u>Potential Health Effects</u> Primary routes of exposure Routes of entry for solids and liquids include eye and skin contact, ingestion and inhalation. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.
<u>Acute Toxicity</u> Ingestion may cause gastrointestinal disturbances.
<u>Irritation</u> Irritating to respiratory system. Irritating to eyes and skin.
<u>Repeated Dose Toxicity</u> Information on propylene glycol – repeated contact with propylene glycol may result in skin sensitization.
<u>Medical Conditions Aggravated by Overexposure</u> Data available do not indicate that there are medical conditions that are generally recognized as being aggravated by exposure to this product. See MSDS Section 11 – Toxicological Information

4. First-Aid Measures
<u>General Advice</u> Remove contaminated clothing



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<u>If Inhaled</u> Remove the individual into fresh air and keep the person calm. Assist in breathing if necessary. Immediate medical attention required.
<u>If on the Skin</u> Wash affected areas thoroughly with soap and water. If irritation develops, seek medical attention.
<u>If in the Eyes</u> In case of contact with the eyes, rinse immediately for at least 15 minutes with plenty of water. If irritation develops, seek medical attention.
<u>If Swallowed</u> Rinse mouth and then drink plenty of water. Induce vomiting. Never induce vomiting or give anything by mouth of the person is unconscious or having convulsions. Immediate medical attention required.
5. Fire-Fighting Measures Flash point – no data available Autoignition – no data available
<u>Suitable Extinguishing Media</u> Water, fog, foam, dry extinguishing media
<u>Hazards During Firefighting</u> No particular hazards known
<u>Protective Equipment for Fire-Fighting</u> Firefighters should be equipped with self-contained breathing apparatus and turn-out gear.
6. Accidental-Release Measures
<u>Personal Precautions</u> Wear appropriate respiratory equipment. Use personal protective clothing. Ensure adequate ventilation.
<u>Environmental Precautions</u> This product is not regulated by RCRA. This product is not regulated by CERCLA (Superfund).
<u>Cleanup</u> Spills should be contained and placed in suitable containers for disposal. Follow applicable State and Federal Regulations.
7. Handling and Storage
<u>Handling</u> Protection against fire and explosion – no explosion proofing necessary
<u>Storage</u> General advice – store at ambient temperature. Keep container tightly closed. Store in a light-impervious container.



Material Safety Data Sheet
Silver Sulfadiazine 1% Cream

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8. Exposure Controls and Personal Protection

Components with Workplace Control Parameters

Silver sulfadiazine – OSHA PEL 0.01 mg/m³ (as silver)
 – ACGIH TWA 0.01 mg/m³ (as silver)

Advice on system design: Provide local exhaust ventilation to control dust.

Personal Protective Equipment

Respiratory protection – Wear a NIOSH-certified (or equivalent) particulate respirator.
 Hand protection – Chemical resistant protective gloves
 Eye protection – Tightly fitting safety goggles (chemical goggles)
 General safety and hygiene measures – Wear protective clothing as necessary to minimize contact. Avoid inhalation of dust. Wash soiled clothing immediately.

9. Physical and Chemical Properties

Form – semi-solid
 Odor – faint odor
 Color – White
 pH value – No data available

10. Stability and Reactivity

Conditions to avoid: Avoid all sources of ignition, heat, sparks, and open flame.
 Substances to avoid: No substances known that should be avoided.
 Hazardous reactions: This product is chemically stable.
 Decomposition products: No hazardous decomposition products known.
 Thermal decomposition: No data available.
 Corrosion to metals: No corrosive effect on metal.

11. Toxicological Information

Acute Toxicity

Oral: No data available concerning acute toxicity.
 Inhalation: Irritating to the respiratory system.
 Dermal: No data available concerning acute toxicity.
 Skin Irritation: Prolonged exposure to the product can result in irritation of the skin and mucous membranes.
 Sensitization: May produce an allergic reaction.

12. Ecological Information

Environmental Fate and Transport

Stability in water: No data available
 Bioaccumulation: No data available

Environmental Toxicity

Acute and prolonged toxicity to fish: No data available concerning fish toxicity.
 Toxicity to aquatic plants: No data available concerning toxicity to algae.
 Toxicity to terrestrial plants: No data available.

13. Disposal Considerations

Waste disposal of substance: Do not discharge substance/product into the sewer



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system. Dispose of according with national, state, and local regulations.
 Container disposal: Dispose of in a licensed facility. Recommend crushing, puncturing, or other means to prevent unauthorized use of used containers.

14. Transport Information

Land transport: Not classified as a dangerous product under transport regulations according to USDOT.
 Sea transport: Not classified as a dangerous good under transport regulations according to IMDG.
 Air transport: Not classified as a dangerous good under transport regulations according to IATA/ICAO.

15. Regulatory Information

Federal Regulations

Registration status: TSCA, US released/exempt
 OSHA hazard category: Chronic target organ effects reported, ACGIH TLV established

<u>CERCLA RQ</u>	<u>CAS Number</u>	<u>Chemical Name</u>
1 pound	22199-08-2	Silver sulfadiazine

SARA hazard categories (EPCRA 3111/312): Acute, chronic
 SARA 313

<u>CAS Number</u>	<u>Chemical Name</u>
22199-08-2	Silver sulfadiazine

State Regulations

State RTK

<u>CAS Number</u>	<u>Chemical Name</u>	<u>State RTK</u>
57-55-6	Propylene glycol	PA
22199-08-2	Silver sulfadiazine	NJ

16. Other Information

HMIS III Rating

Health: 2 Flammability: 1 Physical Hazard: 0

HMIS used a numbering scale ranging from 0 to 4 to indicate the degree of hazard. A value of zero means that the substance possesses essentially no hazard, a rating of 4 indicated high hazard.

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SAFETY DATA SHEET

Section 1: Identification**1.1. Product Identifier**

Speed-Clean

1.2. Recommended Use and Restrictions on Use

Sterilizer Cleaner

1.3. Supplier's Details

Developed For: Midmark Corporation
Address: 60 Vista Drive, P.O. Box 286, Versailles, OH 45380-0286, USA
Telephone: 1-800-MIDMARK

1.4. Emergency Telephone Number:

(937) 526-8498

Section 2: Hazard Identification**2.1. Hazard Classification**

Skin Irritation: Category 2

Eye Irritation: Category 2A

2.2. Label Elements**Signal Word**

Warning

Symbols

Exclamation Mark



GHS07

Hazard Statements

Prolonged or repeated skin contact causes skin irritation

Contact with eyes causes eye irritation

Precautionary Statements**Prevention:**

Wear eye/face protection.

Wear impervious gloves.

Wash hands after handling this material.

Response:

IF IN EYES: Immediately flush eyes with water for 15 minutes, intermittently lifting the lower and upper eyelids.

IF ON SKIN: Flush skin with running water for 15 minutes.

2.3. Hazards Not Otherwise Classified

None

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SAFETY DATA SHEET**Section 3: Composition/Information on Ingredients**

	<u>wt%</u>	<u>CAS Registry #</u>
Water	88 – 92%	7732-18-5
2-Butoxyethanol	<3%	111-76-2
Tetrapotassium pyrophosphate	<2.5%	7320-34-5
Ethoxylated alcohols phosphate ester	<2%	68130-47-2
Tergitol NP-33	≤1%	9016-45-9

Section 4: First Aid Measures**4.1. Description of first aid measures**

Inhalation: Move person to fresh air. If symptoms persist or develop, obtain immediate medical attention.

Skin Contact: Flush skin with running water for 15 minutes. Seek medical attention if irritation persists.

Eye Contact: Immediately flush eyes with water for 15 minutes, intermittently lifting the lower and upper eyelids. If irritation persists, seek immediate medical attention.

Ingestion: Never give anything by mouth to an unconscious person. If conscious and alert, rinse mouth.

Section 5: Fire-Fighting Measures**5.1. Suitable extinguishing media**

Material is non-flammable. Water may be used to fight a fire however, use extinguishing media that is appropriate for the surrounding materials.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

5.3. Special protective actions for fire-fighters

No unusual fire or explosion hazards are anticipated.

Section 6: Accidental Release Measures**6.1. Personal precautions, protective equipment and emergency procedures**

Ventilate the area with fresh air. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental Precautions

Avoid release to the environment. For larger spills, cover drains and build dikes to prevent entry into sewer systems or bodies of water.

6.3. Methods and material for containment and cleaning up

Don appropriate personal protective equipment and then take immediate steps to stop and contain the spill. Contain and recover liquid when possible. Collect material in an appropriate container or absorb with an inert material (vermiculite, dry sand, earth), and place in a chemical waste container.

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SAFETY DATA SHEET**Section 7: Handling and Storage****7.1. Conditions for safe storage including any incompatibles**

Store in a clean, dry, well ventilated area away from incompatible materials (see Section 10). Keep containers closed when not in use. Empty containers may contain residues; therefore, use the same caution when handling empty containers as handling the product. Use product in a well-ventilated area.

Section 8: Exposure Controls/Personal Protection**8.1. Control Parameters**

Chemical Composition/Hazardous Ingredients/Occupational Exposure Limits – exposure limits are time weighted averages (TWA), short-term exposure limits (STEL) and Ceiling (C) and are included if established.

Ingredient	ACGIH TLV	OSHA PEL	IDLH	STEL	NIOSH REL
Water	Not Established	Not Established	Not Established	Not Established	Not Established
2-Butoxyethanol	20 ppm	50 ppm	700 ppm	Not Established	5 ppm
Tetrapotassium Pyrophosphate	Not Established	Not Established	Not Established	Not Established	Not Established
Ethoxylated Alcohols phosphate ester	Not Established	Not Established	Not Established	Not Established	Not Established
Tergitol NP-33	Not Established	Not Established	Not Established	Not Established	Not Established

8.2. Exposure Controls**8.2.1. Engineering Controls**

Use in an area with adequate ventilation. If material is irritating to the respiratory tract or exceeds the TWA, then proper respiratory protection should be worn.

8.2.2 Personal Protective Equipment (PPE)

Eye and Face: Wear splash goggles and face shield if splashing is possible during use. Follow guidelines by OSHA's eye and face protection regulations in 29 CFR 1910.133.

Skin: Prevent skin contact. Wear impervious gloves to prevent skin contact.

Respiratory: Respiratory protection may not be required where adequate ventilation conditions exist. If vapors exist above the PEL, a NIOSH-approved respirator is recommended. If respiratory protection is required, a respiratory program including selection, fit testing, training, maintenance and inspection should be implemented per OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements or European Standard EN 149.

Work Hygienic Practices: Do not eat, drink, or smoke in work area. Always wash hands after handling this material. Maintain good housekeeping.

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SAFETY DATA SHEET**Section 9: Physical and Chemical Properties****9.1. Information on basic physical and chemical properties**

General Physical Form: Liquid
 Color: Clear
 pH: 8
 Flash Point: >200 F

2-Butoxyethanol

Boiling Point: 339 °F
 Freezing Point: -107 °F
 Solubility in Water: Miscible

pH: Not available
 Specific Gravity: 0.90
 Molecular Weight: 118.2

Tetrapotassium Pyrophosphate

Boiling Point: Decomposes
 Freezing Point: N/A
 Solubility in Water: Easily soluble in water

pH: 10
 Specific Gravity: 2.33
 Molecular Weight: 330.34

Ethoxylated alcohols phosphate ester

Boiling Point: N/A
 Freezing Point: N/A
 Solubility in Water: N/A

pH: N/A
 Specific Gravity: N/A
 Molecular Weight: N/A

Section 10: Stability and Reactivity**10.1. Chemical Stability**

Stable

10.2. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.3. Conditions to avoid

Heat and Ignition Sources

10.4. Incompatible materials

Strong oxidizing agents, acids, ammonia, organic amines, chlorates, chlorine, and reducing agents

10.5. Hazardous Decomposition

Carbon Monoxide, Carbon Dioxide, Oxides of Phosphorus, and irritating fumes and gases

Section 11: Toxicological Information**11.1. Teratology**

No information available

11.2. Reproduction

High doses of 2-Butoxyethanol may cause reproductive problems and birth defects in animals.

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11.3. Mutagenicity

No information available

2-ButoxyethanolAcute Dermal Toxicity – (rabbit) LD₅₀ = 100-610 mg/kgAcute Inhalation Toxicity – (rat) LC₅₀ = 450-486 ppm (4H)Acute Oral Toxicity – (rat) LD₅₀ = 530-3000 mg/kg

Section 12: Ecological Information**Section 12.1.**

ECOTOXICOLOGICAL INFORMATION:

2-ButoxyethanolAcute/Prolonged Toxicity to Fish – (oyster) 4d LC₅₀ = 89 mg/LAcute Toxicity to Aquatic Invertebrates – (*Daphnia*) 2d LC₅₀ = 835 mg/LToxicity to Aquatic Plants – (algae) 7d EC₅₀ > 1000 mg/L

Chronic Toxicity to Fish – (Flathead minnow) 32d MATC = 135 mg/L

Fate: In the air this material is expected to readily degrade. Not expected to be toxic to aquatic life.

Tetrapotassium pyrophosphateAcute Toxicity to Fish – (Zebra Mussel) 24h LC₅₀ = 72 mg/L

Section 13: Disposal Considerations**Section 13.1.**

DISPOSAL METHOD: Disposal must be in accordance with applicable federal, state and local governmental regulations. Recycling of the material is preferred.

Section 13.2.

PRODUCT DISPOSAL: Refer to US EPA guidelines for the classification listed in 40 CFR 261.3.

Section 13.3.

EMPTY CONTAINER: Empty containers may contain residue. Use safety measures when handling empty containers.

Section 13.4.

GENERAL COMMENTS: Recovery and recycling of the materials is preferred.

Section 14: Transport Information**Section 14.1.**

SPECIAL SHIPPING NOTES: This product is not regulated by the Department of Transportation

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Section 15: Regulatory Information**Section 15.1.**

CERCLA (COMPREHENSIVE EMERGENCY RESPONSE, COMPENSATION, AND LIABILITY ACT): None are found CERCLA Priority List of Hazardous Chemicals, or on the EPA List of Lists (EPCRA) list.

Section 15.2.

TSCA (TOXIC SUBSTANCE CONTROL ACT)

TSCA Regulatory: 2-Butoxyethanol; Tergitol NP-33; & Tetrapotassium pyrophosphate are listed on the TSCA list.

Section 15.3.

RCRA STATUS: None are found on RCRA P-Series or U-Series.

Section 15.4.

CLEAN WATER ACT: None of the components are listed as a Priority Pollutant or a Toxic Pollutant under the Clean Water Act.

Section 15.5.

CANADA:

All components are found on the DSL/NDL list.

Section 16: Other Information

REVISION INFORMATION:

Approved by: Environmental Health and Safety Manager
Approval date: June 2018

REFERENCES:

1. 2010 National Institute of Occupational Safety and Health (NIOSH) Pocket Guide to Chemical Hazards
2. 2007 Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, ACGIH
3. Department of Transportation Emergency Response Guidebook –2012
4. Code of Federal Regulation (CFR) 29, 40, and 49
5. Toxnet online database
6. Mallinckrodt Baker, Inc. online MSDS database
7. NTP online toxicology database
8. CDC.gov website for toxicological data
9. EPA Title III List of Lists – 2012
10. Toxic Substance Control Act Chemical Inventory List
11. Pesticide Action Network – Pesticide Database
12. International Programme on Chemical Safety, INCHEM website

MANUFACTURER DISCLAIMER:

Our purpose in sending this information is to help you protect the health and safety of your personnel. The information in this Material Safety Data Sheet meets or exceeds the requirements of the United States Occupational Safety and Health Act and Regulation promulgated thereunder (29 CFR 1910.1200 et. Seq.). Midmark Corporation believes the information present herein is based on reliable and accurate data gathered as of the date of the Safety Data Sheet. Midmark Corporation provides no warranty or representation and disclaims all liability for the accuracy or completeness of the provided information.

Safety Data Sheet



Section 1: Identification

Product identifier

Product Name • **Tetracaine Hydrochloride Ophthalmic Solution, 0.5%**

Product Code • AB09111; Core No. 091; NDC 24208-920-64

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

Recommended use • Finished Pharmaceutical Product; For procedures in which a rapid and short-acting topical ophthalmic anesthetic is indicated such as in tonometry, gonioscopy, removal of corneal foreign bodies, conjunctival scraping for diagnostic purposes, suture removal from the cornea, other short corneal and conjunctival procedures.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com

Telephone (General) • 1-800-553-5340

Emergency telephone number

Manufacturer • 1-800-535-5053 - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • No data available

Label elements

UN GHS

WARNING



Hazard statements • Anesthetic effect on eyes
May cause eye irritation

May cause serious eye damage

Precautionary statements

- Prevention** • Use personal protective equipment as required.
Wash thoroughly after handling.
- Response** • IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
- Storage/Disposal** • Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

Other hazards

- UN GHS**
- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Boric acid	CAS:10043-35-3 EINECS:233-139-2	1% TO 5%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1
Chlorobutanol	CAS:57-15-8 EINECS:200-317-6	0.4%	UN GHS: NDA
Edetate Disodium Dihydrate	CAS:139-33-3 EINECS:205-358-3	< 0.1%	UN GHS: NDA
Potassium chloride	CAS:7447-40-7 EINECS:231-211-8	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; STOT RE 1
Tetracaine Hydrochloride	CAS:136-47-0 EINECS:205-248-5	0.5%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Classification criteria not met

Hydrochloric Acid (CAS:7647-01-0, EINECS:231-595-7) and/or Sodium Hydroxide (CAS# 1310-73-2, EINECS: 215-185-5) may be added to adjust the pH.

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

Eye

- For accidental and non-therapeutic applications, flush eyes with copious amounts of

Ingestion

water for at least 15 minutes. Get medical attention if eye irritation persists.

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- 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.

Indication of any immediate medical attention and special treatment needed**Notes to Physician**

- May cause temporary stinging, burning, and conjunctival redness. After installation, the eye may be scratched without pain, so should not be rubbed. May cause hypersensitivity.

Section 5: Fire-Fighting Measures**Extinguishing media**

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known - product is not flammable or combustible.

Hazardous Combustion Products • No data available

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures**Personal precautions, protective equipment and emergency procedures**

Personal Precautions • No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Refer to Section 8.

Emergency Procedures • No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available

Methods and material for containment and cleaning up

Containment/Clean-up Measures • Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

Section 7 - Handling and Storage**Precautions for safe handling**

Handling • No special handling is required. Refer to Section 8. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities**Storage**

- Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection**Control parameters****Exposure Limits/Guidelines**

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines		
	Result	ACGIH
Boric acid (10043-35-3)	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)
	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)

Exposure Control Notations**ACGIH**

- Boric acid (10043-35-3): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (listed under Borate compounds, inorganic))

Exposure controls**Engineering Measures/Controls**

- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment**Respiratory**

- No respiratory protection required during normal handling.

Eye/Face

- Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn. Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging.

Hands

- Gloves are not required under normal handling conditions.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties**Information on Physical and Chemical Properties**

Material Description			
Physical Form	Liquid	Color	Colorless to slightly yellow.
Odor	Camphor-like	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	3.7 to 6
Specific Gravity/Relative Density	= 1.008	Water Solubility	Soluble
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	No data available		

Flammability

Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant

Environmental

Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity**Reactivity**

- No dangerous reactions known.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information**Information on toxicological effects**

- Other Material Information**
- Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Components		
Tetracaine Hydrochloride (0.5%)	136-47-0	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 160 mg/kg; Behavioral: Muscle weakness; Lungs, Thorax, or Respiration: Respiratory depression; Lungs, Thorax, or Respiration: Other changes
Boric acid (1% TO 5%)	10043-35-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2500 mg/kg; Behavioral: Convulsions or effect on seizure threshold; Behavioral: Ataxia
Potassium chloride (< 1%)	7447-40-7	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2600 mg/kg
Edetate Disodium Dihydrate (< 0.1%)	139-33-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2 g/kg
Chlorobutanol (0.4%)	57-15-8	Acute Toxicity: Ingestion/Oral-Rat LD50 • 510 mg/kg

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met

Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Irritation 2A

Potential Health Effects

Inhalation

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • No data available.

Skin

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • No data available.

Eye

- Acute (Immediate)** • Transient symptoms (signs) such as stinging, burning and conjunctival redness may occur.
- Chronic (Delayed)** • Prolonged use results in diminished duration of anesthesia and retarded healing. This may cause the drug to be used more frequently creating a "vicious circle". Subsequent corneal infection and/or corneal opacification with accompanying permanent visual loss or corneal perforation may occur.

Ingestion

- Acute (Immediate)** • Small amounts (less than a tablespoonful) swallowed are not likely to cause injury: swallowing amounts larger than that may cause gastrointestinal irritation.
- Chronic (Delayed)** • No data available.

Carcinogenic Effects		
	CAS	NTP
Boric acid	10043-35-3	Evidence of Carcinogenicity

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

- Product waste** • Waste characterizations and compliance with applicable laws are the responsibility

Packaging waste

- solely of the waste generator.
- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

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

SARA Hazard Classifications • No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Chlorobutanol	57-15-8	Yes	Yes	Yes
Edetate Disodium Dihydrate	139-33-3	Yes	Yes	Yes
Tetracaine Hydrochloride	136-47-0	Yes	Yes	No
Boric acid	10043-35-3	Yes	Yes	Yes
Potassium chloride	7447-40-7	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada**Labor****Canada - WHMIS - Classifications of Substances**

• Edetate Disodium Dihydrate	139-33-3	Uncontrolled product according to WHMIS classification criteria (including 3.5%)
• Potassium chloride	7447-40-7	Uncontrolled product according to WHMIS classification criteria (including 23.8%)
• Boric acid	10043-35-3	D2A
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS

		classification criteria
Canada - WHMIS - Ingredient Disclosure List		
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	1 %
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	Repr.Cat.2; R60-61
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Concentration Limits

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	5.5%≤C: Repr.Cat.2; R:60-61
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	T R:60-61 S:53-45
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	S:53-45
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

United States

Environment

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	Not Listed
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	Not Listed
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	Not Listed
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	Not Listed
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	Not Listed
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

Section 16 - Other Information**Last Revision Date**

- 13/May/2015

Preparation Date

- 13/May/2015

Disclaimer/Statement of Liability

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Safety Data Sheet

Tincture of Benzoin Pump Sprayer

1. Identification

1.1. Product identifier

Product Identity

Tincture of Benzoin Pump Sprayer

Alternate Names

Tincture of Benzoin Pump Sprayer

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

Intended use

Skin Preparation

Application Method

See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet

Company Name

Smith & Nephew
970 Lake Carillon Drive, Suite 110
St. Petersburg, FL 33716

Emergency

Customer Service: Smith & Nephew

1-800-876-1261

2. Hazard(s) identification

2.1. Classification of the substance or mixture

Flam. Liq. 2;H225	Highly Flammable liquid and vapor.
Skin Irrit. 3;H316	Causes mild skin irritation. (Not adopted by US OSHA)
Eye Irrit. 2;H319	Causes serious eye irritation.
Skin Sens. 1;H317	May cause an allergic skin reaction.
STOT SE 3;H336	May cause drowsiness or dizziness.

2.2. Label elements

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



Danger

H225 Highly flammable liquid and vapor.
H316 Causes mild skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H336 May cause drowsiness and dizziness.

Safety Data Sheet

Tincture of Benzoin Pump Sprayer

[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.

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

P280 Wear protective gloves / eye protection / face protection.

[Response]:

P302+352 IF ON SKIN: Wash with plenty of soap and water.

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.

P313 Get medical advice / attention.

P321 Specific treatment (see information on this label).

P333+313 If skin irritation or a rash occurs: Get medical advice / attention.

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.

P363 Wash contaminated clothing before reuse.

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.

Safety Data Sheet

Tincture of Benzoin Pump Sprayer

3. Composition/information on ingredients

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
Isopropyl Alcohol CAS Number: 0000067-63-0	75 - 100	Flam. Liq. 2;H225 Eye Irrit. 2;H319 STOT SE 3;H336	[1][2]
Gum benzoin CAS Number: 0009000-05-9	1.0 - 10	Skin Irrit. 2;H315 Skin Sens. 1;H317 Eye Irrit. 2;H319 Aquatic Chronic 3;H412	[1]

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.

[2] Substance with a workplace exposure limit.

[3] PBT-substance or vPvB-substance.

*The full texts of the phrases are shown in Section 16.

4. First aid measures

4.1. Description of first aid measures

General

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

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.

Eyes

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

Skin

No first aid should be needed.

Ingestion

Do not induce vomiting. Contact the poison control center or a physician immediately for instructions.

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

Overview

Acute Effects

Inhalation: Exposure to high air concentrations may cause mild irritation to nose and throat. Drowsiness, headache, and mild narcosis can occur from inhalation.

Eye: Exposure to high air concentrations may cause mild irritation to eyes.

Ingestion: Ingestion may cause drowsiness, burning of the gastrointestinal tract, and death. Ingestion may cause gastrointestinal pain, cramps, nausea and vomiting.

Medical Conditions Aggravated by Long-Term Exposure: Pre-existing eye, skin and respiratory disorders may be aggravated by exposure to this product. Impaired function from pre-existing disorders may be aggravated by exposure to this product.

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

Safety Data Sheet

Tincture of Benzoin Pump Sprayer

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.

Skin

May cause an allergic skin reaction. Causes mild skin irritation. (Not adopted by US OSHA)

5. Fire-fighting measures

5.1. Extinguishing media

Carbon dioxide, dry chemical, alcohol foam

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: Oxides of Carbon and unidentified organic compounds.

Keep away from heat / sparks / open flames / hot surfaces - No smoking.

Keep cool.

Ground / bond container and receiving equipment.

Use explosion-proof electrical / ventilating / light / equipment.

Use only non-sparking tools.

Take precautionary measures against static discharge.

Avoid breathing dust / fume / gas / mist / vapors / spray.

5.3. Advice for fire-fighters

Vapors are heavier than air and may travel along the ground to some distant source of ignition and flash back.

Wear self-contained breathing apparatus and protective clothing.

ERG Guide No. 128

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

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

6.3. Methods and material for containment and cleaning up

Mop or wipe up small spills. Ventilate area.

Safety Data Sheet

Tincture of Benzoin Pump Sprayer

Dike large spills to minimize contamination and contain material. Remove all sources of heat and ignition. Absorb with sand or vermiculite. Ventilate area to dissipate vapors.

7. Handling and storage

7.1. Precautions for safe handling

Store in accordance with the National Fire Protection Association's publication NFPA 30, Flammable and Combustible Liquids Code. 29 CFR 1910.106 applies to the handling, storage, and use of flammable and combustible liquids.

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

7.2. Conditions for safe storage, including any incompatibilities

Handle containers carefully to prevent damage and spillage.

Incompatible materials: Strong oxidizing agents

Store in a cool ($\leq 77^{\circ}\text{F}$ / 25°C), dry, well-ventilated area away from strong oxidizing agents, sources of heat, sparks, and open flames.

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

7.3. Specific end use(s)

No data available.

8. Exposure controls and personal protection

8.1. Control parameters

Exposure

CAS No.	Ingredient	Source	Value
0000067-63-0	Isopropyl Alcohol	OSHA	TWA 400 ppm (980 mg/m ³) STEL 500 ppm
		ACGIH	TWA: 200 ppm STEL: 400 ppm Revised 2003,
		NIOSH	TWA 400 ppm (980 mg/m ³) ST 500 ppm (1225 mg/m ³)
		Supplier	No Established Limit
0009000-05-9	Gum benzoin	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

Carcinogen Data

CAS No.	Ingredient	Source	Value
0000067-63-0	Isopropyl Alcohol	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;
0009000-05-9	Gum benzoin	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

Safety Data Sheet

Tincture of Benzoin Pump Sprayer

8.2. Exposure controls

Respiratory	When working with small quantities in a well-ventilated area, respiratory protection may not be required.
Eyes	None required for normal use.
Skin	When working with small quantities in a well-ventilated area, protective clothing/equipment may not be required.
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.
Other Work Practices	Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

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

9. Physical and chemical properties

Appearance	Transparent amber Liquid
Odor	Characteristic
Odor threshold	Not determined
pH	Not determined
Melting point / freezing point	-127°F (Isopropyl Alcohol)
Initial boiling point and boiling range	180°F (Isopropyl Alcohol)
Flash Point	53°F / 11.7°C TCC
Evaporation rate (Ether = 1)	1.4 (Isopropyl Alcohol; nBuAc = 1)
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: 2.5 Upper Explosive Limit: 12
Vapor pressure (Pa)	32 mmHg @ 68°F (Isopropyl Alcohol)
Vapor Density	2.1 (Isopropyl Alcohol; Air = 1)
Specific Gravity	0.85 @ 25°C (H2O = 1)
Solubility in Water	Miscible
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not determined
Decomposition temperature	Not available
Viscosity (cSt)	Not determined
VOC Content	Not available
% Volatile	93%

9.2. Other information

No other relevant information.

Safety Data Sheet

Tincture of Benzoin Pump Sprayer

10. Stability and reactivity

10.1. Reactivity

Hazardous Polymerization will not occur.

10.2. Chemical stability

Stable under normal circumstances.

10.3. Possibility of hazardous reactions

Carbon monoxide and unidentified organic compounds may be formed during combustion.

10.4. Conditions to avoid

Avoid excessive heat, open flames and all ignition sources.

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

Oxides of Carbon

11. Toxicological information

Acute toxicity

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.

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Isopropyl Alcohol - (67-63-0)	4,710.00, Rat - Category: 5	12,800.00, Rat - Category: NA	72.60, Rat - Category: NA	No data available	No data available
Gum benzoin - (9000-05-9)	No data available	No data available	No data available	No data available	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).

Safety Data Sheet

Tincture of Benzoin Pump Sprayer

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	3	Causes mild skin irritation. (Not adopted by US OSHA)
Serious eye damage/irritation	2	Causes serious eye irritation.
Respiratory sensitization	---	Not Applicable
Skin sensitization	1	May cause an allergic skin reaction.
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	3	May cause drowsiness or dizziness.
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

12. Ecological information

12.1. Toxicity

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. See section 3 for details

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
Isopropyl Alcohol - (67-63-0)	1,400.00, <i>Lepomis macrochirus</i>	100.00, <i>Daphnia magna</i>	100.00 (72 hr), <i>Scenedesmus subspicatus</i>
Gum benzoin - (9000-05-9)	Not Available	Not Available	Not Available

12.2. Persistence and degradability

There is no data available on the preparation itself.

12.3. Bioaccumulative potential

Not Measured

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects

No data available.

Safety Data Sheet

Tincture of Benzoin Pump Sprayer

13. Disposal considerations

13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

14. Transport information

Notes:

1. May qualify for transportation under 'Limited Quantities' and/or 'Excepted Quantities' provisions. Consult applicable DOT, IMDG, IATA/ICAO regulations depending on transportation mode.
2. May qualify for transportation under 'Consumer Commodity ORM-D' provisions. Consult applicable DOT, IMDG, IATA/ICAO regulations depending on transportation mode.

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	UN1993	UN1993	UN1993
14.2. UN proper shipping name	UN1993, Flammable liquids, n.o.s., (Isopropyl Alcohol), 3, II	Flammable liquids, n.o.s., (Isopropyl Alcohol)	Flammable liquids, n.o.s., (Isopropyl Alcohol)
14.3. Transport hazard class(es)	DOT Hazard Class: 3	IMDG: 3 Sub Class: Not Applicable	Air Class: 3
14.4. Packing group	II	II	II
14.5. Environmental hazards			
IMDG	Marine Pollutant: No		
14.6. Special precautions for user	No further information		

15. Regulatory information

Regulatory Overview	The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.
Toxic Substance Control Act (TSCA)	All components of this material are either listed or exempt from listing on the TSCA Inventory.
WHMIS Classification	B2 D2B
US EPA Tier II Hazards	Fire: Yes Sudden Release of Pressure: No Reactive: No Immediate (Acute): Yes Delayed (Chronic): No

EPCRA 311/312 Chemicals and RQs:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 302 Extremely Hazardous:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 313 Toxic Chemicals:

Isopropyl Alcohol

Safety Data Sheet

Tincture of Benzoin Pump Sprayer

Proposition 65 - Carcinogens (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Developmental Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

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

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

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

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

New Jersey RTK Substances (>1%):

Isopropyl Alcohol

Pennsylvania RTK Substances (>1%):

Isopropyl Alcohol

16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

H225 Highly flammable liquid and vapor.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H336 May cause drowsiness and dizziness.

H412 Harmful to aquatic life with long lasting effects.

This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.

End of Document



SAFETY DATA SHEET (SDS)

SDS Date: 1.23.2019

Section 1: IDENTIFICATION

TRADE NAME Topical Anesthetic Spray (3.5oz canisters) PRODUCT ID 140-MED & 140-MST		DISTRIBUTED BY McKesson Medical Surgical 9945 Mayland Drive Richmond, VA 23233
CHEMICAL NAME 1,1,1,3,3-Pentafluoropropane 1,1,1,2-Tetrafluoroethane	CONTACT INFORMATION 800-777-4908 Monday – Friday 8am-6pm EST	
RECOMMENDED USE Topical Anesthetic	IN CASE OF EMERGENCY 1-800-451-8346 3E Company (Day or Night)	
FORMULA CHF ₂ CH ₂ CF ₃ / CH ₂ FCF ₃	CHEMICAL FAMILY Halogenated Hydrocarbon	

Section 2: HAZARDS IDENTIFICATION

Health Rating Flammability Rating Reactivity Rating Special Rating Lab Protective Equipment		2 - Moderate 0 - None 1 - Moderate None Neoprene or Viton gloves, lab coat, goggles or face shield, vent hood.		
Hazard Category	Signal Word	Hazard Statement	Pictogram	Precautionary Statement
Compressed Gas	Warning	Contains gas under pressure; may explode if heated		Store in a well-ventilated place.
Eye Irritation (Category 2B)	Warning	Causes eye irritation	N/A	If product gets into eyes, see the Section 4: First Aid Measures.
Cause		Effects		
Potential Acute Health Effects	Inhalation	When oxygen levels in air are reduced to 12-14% by displacement, symptoms of asphyxiation, loss of coordination, increased pulse rate and deeper respiration will occur. At high levels, cardiac arrhythmia may occur.		
	Ingestion	Unlikely route of exposure due to gaseous nature. Discomfort due to volatility would be expected.		
	Eye Contact	Liquid contact can cause irritation and frostbite.		
	Skin Contact	Over application could cause frostbite. Liquid contact is non-irritating.		

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	Concentration	OSHA PEL	ACGIH TLV-TWA
1,1,1,3,3-Pentafluoropropane	460-73-1	95%	None	None
1,1,1,2-Tetrafluoroethane	811-97-1	5%	None	None

Section 4: FIRST AID MEASURES

Inhalation	Immediately remove patient to fresh air. If breathing has stopped, give artificial respiration. Use oxygen as required, provided a qualified operator is available. DO NOT give epinephrine (adrenaline). Get medical attention immediately.
Ingestion	Unlikely route of exposure due to gaseous nature. DO NOT induce vomiting unless instructed to do so by a physician. DO NOT give stimulants. Get medical attention immediately.
Skin Contact	If there is evidence of frostbite seek medical attention.
Eye Contact	Immediately flush eyes with copious amounts of water for at least 15 minutes (in case of frostbite water should be lukewarm, not hot) lifting lids occasionally to facilitate irrigation. Get medical attention.

Section 5: FIRE FIGHTING MEASURES

Special Fire Fighting Procedures

Fire fighters should wear self-contained, NIOSH approved breathing apparatus for protection against possible toxic decomposition products. Proper eye and skin protection should be provided. Use spray to keep fire-exposed containers cool.

Unusual Fire and Explosion Hazards

Not flammable at ambient temperatures and atmospheric pressure. However this material will become combustible when mixed with air under pressure and exposed to strong ignition sources contact with certain reactive metals may result in formation of explosive or exothermic reactions under specific conditions (e.g. very high temperatures and/or appropriate pressures).

Section 6: ACCIDENTAL RELEASE MEASURES

Spill and Leak Response

If a large quantity of containers the product has been released, evacuate unprotected personnel. Protected personnel should eliminate all sources of ignition and shut off leak, if without risk, and provide ventilation.

Waste Disposal Method

Comply with federal, state and local laws.

Section 7: HANDLING AND STORAGE			
Storage Precautions Store in cool, dry, well ventilated area of low fire risk. Protect against physical damage. Do not subject to temperatures above 120°F (50°C).			
Handling Precautions Use in well-ventilated areas. Do not use near temperatures above 120°F (50°C).			
Section 8: EXPOSURE CONTROLS PERSONAL PROTECTION			
Engineering Controls	Provide local ventilation at filling zones and where leakage is probable. Use with adequate ventilation.		
Respiratory Protection	None generally required for adequately ventilated work situations. For accidental release in confined space, where the concentration may be above the PEL of 1,000 ppm, use a NIOSH approved, self contained, positive pressure respirator for emergencies and in situations where air may be displaced by vapors.		
Skin Protection	Use protective, impervious gloves and clothing made of neoprene, nitrile or butyl rubber if prolonged or repeated contact with liquid is anticipated. Wash clothing promptly, if wet. Remove any non-impervious clothing and wash before re-use.		
Eye Protection	For normal conditions, wear safety glasses. Where there is reasonable probability of liquid contact, wear splash-proof goggles. Contact lenses should not be worn under such conditions.		
Exposure Limits	OSHA PEL: None		

SAFETY DATA SHEET



Virex TB Ready-To-Use Disinfectant Cleaner

Version Number: 1

Preparation date: 2014-10-09

1. IDENTIFICATION

Product name: Virex TB Ready-To-Use Disinfectant Cleaner
Product Code: 04743
SDS #: MS0800547
Recommended use:

- Industrial/Institutional
- Disinfectant
- This product is intended to be used neat.

Uses advised against: Uses other than those identified are not recommended

Manufacturer, importer, supplier:

US Headquarters Diversey, Inc. 8310 16th St. Sturtevant, Wisconsin 53177-1964 Phone: 1-888-352-2249 MSDS Internet Address: www.diversey.com	Canadian Headquarters Diversey, Inc. - Canada 3755 Laird Road Mississauga, Ontario L5L 0B3 Phone: 1-800-668-3131

Emergency telephone number: 1-800-851-7145 (U.S.); 1-651-917-6133 (Int'l)

2. HAZARDS IDENTIFICATION

Classification for the undiluted product

Serious eye damage/eye irritation	Category 2A

**Signal Word:****Warning****Precautionary Statements****CAUSES SERIOUS EYE IRRITATION.**

Avoid contact with eyes, skin and clothing. Wash affected areas thoroughly after handling. May cause irritation to mouth, throat and stomach. Wear chemical-splash goggles and chemical-resistant gloves. IF SWALLOWED: Rinse mouth. Drink a cupful of milk or water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. If eye irritation persists: Get medical advice or attention. Dispose of in accordance with all federal, state and local applicable regulations. SUPPLEMENTAL INFORMATION. May be mildly irritating to skin. In case of contact, immediately flush with plenty of water. If irritation occurs and persists, get medical attention.

Health hazards not otherwise classified (HHNOC) - Not applicable**Physical hazards not otherwise classified (PHNOC)** - Not applicable

Classification for the diluted product @ RTU

This product is intended to be used neat.

Precautionary Statements

See undiluted product information above.

3. COMPOSITION/INFORMATION ON INGREDIENTS**Classified Ingredients**

Ingredient(s)	CAS #	Weight %
Diethylene glycol butyl ether	112-34-5	5 - 10%
Tetrasodium salt of EDTA	64-02-8	1% - < 3%
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	68391-01-5	> 0.1% - < 1%
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	68956-79-6	> 0.1% - < 1%

*Exact percentages are being withheld as trade secret information

4. FIRST AID MEASURES**Undiluted Product:**

Eyes: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

Skin: In case of contact, immediately flush with plenty of water. If irritation occurs and persists, get medical attention.

Inhalation: No specific first aid measures are required.

Ingestion: IF SWALLOWED: Rinse mouth. Drink a cupful of milk or water.

Most Important Symptoms/Effects: No information available.

Immediate medical attention and special treatment needed: Not applicable.

Aggravated Medical Conditions: Persons with pre-existing skin disorders may be more susceptible to irritating effects.

Diluted Product:

This product is intended to be used neat.

Eyes: See undiluted product information above.

Skin: See undiluted product information above.

Inhalation: See undiluted product information above.

Ingestion: See undiluted product information above.

5. FIRE-FIGHTING MEASURES**Specific methods:**

No special methods required

Suitable extinguishing media:

The product is not flammable. Extinguish fire using agent suitable for surrounding fire.

Specific hazards:

Not applicable.

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

Extinguishing media which must not be used for safety reasons: No information available.

6. ACCIDENTAL RELEASE MEASURES**Personal precautions:**

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

Environmental precautions

Clean-up methods - large spillage. Soak up with inert absorbent material. Sweep up and shovel into

and clean-up methods:

suitable containers for disposal. Use a water rinse for final clean-up.

7. HANDLING AND STORAGE

Handling: Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Do not taste or swallow. FOR COMMERCIAL AND INDUSTRIAL USE ONLY.

Storage:

Protect from freezing. Keep tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

Aerosol Level (if applicable) : Not applicable

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

Ingredient(s)	CAS #	ACGIH	OSHA
Diethylene glycol butyl ether	112-34-5	10 ppm (TWA)	-
Tetrasodium salt of EDTA	64-02-8	-	-
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	68956-79-6	-	-
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	68391-01-5	-	-

Undiluted Product:**Engineering measures to reduce exposure:**

No special ventilation requirements General room ventilation is adequate

Personal Protective Equipment

Eye protection:	Chemical-splash goggles.
Hand protection:	Chemical-resistant gloves.
Skin and body protection:	No special requirements under normal use conditions.
Respiratory protection:	No special requirements under normal use conditions.
Hygiene measures:	Handle in accordance with good industrial hygiene and safety practice.

Diluted Product:

This product is intended to be used neat.

Personal Protective Equipment

Eye protection:	Chemical-splash goggles.
Hand protection:	Chemical-resistant gloves.
Skin and body protection:	No special requirements under normal use conditions.
Respiratory protection:	No special requirements under normal use conditions.
Hygiene measures:	Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Liquid

Evaporation Rate: No information available

Odor threshold: No information available.

Melting point/range: Not determined

Autoignition temperature: No information available

Solubility in other solvents: No information available

Density: 8.44 lbs/gal 1.012 Kg/L

Bulk density: No information available

Flash point: > 200 °F > 93.3 °C

Dilution Flash Point: > 200 °F > 93.3 °C

Elemental Phosphorus: 0 % by wt.

pH: 12.2

Dilution pH: 12.2 @ RTU

Metal Corrosion: Not determined

Explosion limits: - upper: Not determined - lower: Not determined

Color: Clear, Colorless

Odor: Lemon Citrus

Boiling point/range: Not determined

Decomposition temperature: Not determined

Solubility: Completely Soluble

Relative Density (relative to water): 1.012

Vapor density: No information available

Vapor pressure: No information available.

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

Viscosity: No information available

VOC: 0.06 % *

VOC % by wt. at use dilution 0.06 % *

Flammability (Solid or Gas): Not applicable

* - Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Article 2, Consumer Products, Sections 94508

10. STABILITY AND REACTIVITY

Reactivity:

Not Applicable

Stability:

The product is stable

Hazardous decomposition products:

Nitrogen oxides (NOx).

Materials to avoid:

Acids. Oxidizing agents.

Conditions to avoid:

No information available.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:

Eye contact, Skin contact, Inhalation

Delayed, immediate, or chronic effects and symptoms from short and long-term exposure

Skin contact: May be mildly irritating to skin. Symptoms may include redness and/or transient discomfort.

Eye contact: Causes serious eye irritation. Symptoms may include pain, redness, and watering.

Ingestion: May be irritating to mouth, throat and stomach. Symptoms may include stomach pain and nausea.

Inhalation: May be irritating to nose, throat, and respiratory tract. Symptoms may include coughing and difficulty breathing.

Sensitization: No known effects.

Numerical measures of toxicity

ATE - Oral (mg/kg): >5000

ATE - Inhalatory, mists (mg/l): >20

12. ECOLOGICAL INFORMATION

Ecotoxicity: No information available.

Persistence and Degradability: No information available.

Bioaccumulation: No information available.

13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products: PESTICIDAL WASTE - Observe all applicable Federal/Provincial/State regulations and Local/Municipal ordinances regarding disposal of pesticide wastes. This product, as sold, if discarded or disposed, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Dispose in compliance with all Federal, state, provincial, and local laws and regulations.

Contaminated Packaging: Do not re-use empty containers.

RCRA Hazard Class (undiluted product): Not Regulated

14. TRANSPORT INFORMATION

DOT/TDG/IMDG: Please refer to the Diversey HazMat Library, only available through Internet Explorer, <http://naextranet.diversey.com/dot/>, for up to date shipping information.

DOT (Ground) Bill of Lading Description: DISINFECTANTS

IMDG (Ocean) Bill of Lading Description: DISINFECTANTS

15. REGULATORY INFORMATION

International Inventories at CAS# Level

All components of this product are listed on the following inventories: U.S.A. (TSCA).

U.S. Regulations

EPA Reg. No. : 70627-2

This chemical is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use.

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and aquatic invertebrates.

California Proposition 65: This product is not subject to the reporting requirements under California's Proposition 65.

RIGHT TO KNOW (RTK)

Ingredient(s)	CAS #	MARTK:	NJRTK:	PARTK:	RIRTK:
Water	7732-18-5	-	-	-	-
Diethylene glycol butyl ether	112-34-5	-	X	-	-
Tetrasodium salt of EDTA	64-02-8	-	-	-	-
Alcohol ethoxylates	68131-39-5	-	-	-	-
Sodium metasilicate	6834-92-0	-	-	-	-
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	68391-01-5	-	-	-	-
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	68956-79-6	-	-	-	-

CERCLA/ SARA

Ingredient(s)	CAS #	Weight %	CERCLA/SARA RQ (lbs)	Section 302 TPQ (lbs)	Section 313
Diethylene glycol butyl ether	112-34-5	5 - 10%			X

Ingredient(s)	CAA HAP	CAA ODS	CWA Priority Pollutants
Diethylene glycol butyl ether	X		

SARA 311/312 Hazard Categories

Immediate:	x
Delayed:	-
Fire:	-
Reactivity:	-
Sudden Release of Pressure:	-

Canada

WHMIS hazard class: Not for sale in Canada.

Ingredient(s)	CAS #	NPRI
Diethylene glycol butyl ether	112-34-5	X

16. OTHER INFORMATION**NFPA (National Fire Protection Association)**

Rating Scale: (Low Hazard) 0 - 4 (Extreme Hazard)

Health 2

Flammability 0

Instability 0

Version Number: 1

Preparation date: 2014-10-09

Reason for revision:

Not applicable

Prepared by:

NAPRAC

Additional advice:

• Contains an added fragrance, see "Odor" heading in section 9 for specific description

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**SDS: XOPENEX® (levalbuterol hydrochloride)
Inhalation Solution**

SAFETY DATA SHEET

1. Identification

Product Identifier:	XOPENEX® (levalbuterol hydrochloride) Inhalation Solution
Synonyms:	Levalbuterol; levalbuterol Hydrochloride, (R)-Albuterol hydrochloride; (R)-a-[[[1-Dimethylethyl)amino]methyl]-4-hydroxy-1,3-benzenedimethanol hydrochloride; R-a-[(tert-Butylamino)methyl]-4-hydroxy-m-xylene-a,a'-diol hydrochloride; Levosalbutamol hydrochloride; (R)-Salbutamol hydrochloride.
National Drug Code (NDC):	17478-172-24 17478-173-24 17478-174-24 17478-171-30
Recommended Use:	Pharmaceutical.
Company:	Oak Pharmaceuticals, Inc. (Subsidiary of 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:	None required.
Health Hazards:	None required.
Signal Word:	None required.
Hazard Statement(s):	None required.
Precautionary Statement(s):	None required.
Hazards Not Otherwise Classified:	None required.
Supplementary Information:	Xopenex® Inhalation Solution contains levalbuterol hydrochloride, the (R)-enantiomer of albuterol, which is a highly potent and relatively selective b2- adrenergic agonist. It is used as a bronchodilator. Frequently reported adverse effects associated with use by inhalation are commonly seen with b2-agonists, and include dizziness, cardiovascular effects (changes in blood pressure or heart rate, and abnormal ECG patterns), metabolic imbalance, and sore nose and throat. There have also been occasional reports of anaphylactic reaction, hives, swelling, rash, and potentially life-threatening paradoxical bronchospasm.



SDS: XOPENEX® (levalbuterol hydrochloride)
Inhalation Solution

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Levalbuterol Hydrochloride	50293-90-8	Levalbuterol; levalbuterol Hydrochloride, (R)-Albuterol hydrochloride; (R)-a-[[[1-Dimethylethyl)amino]methyl]-4-hydroxy-1,3-benzenedimethanol hydrochloride; R- a-[(tert-Butylamino) methyl]-4-hydroxy-m-xylene-a,a'-diol hydrochloride; Levosalbutamol hydrochloride; (R)-Salbutamol hydrochloride.	$C_{13}H_{21}NO_3 \cdot HCl$	275.8	0.01-0.05%

*The formula also contains Sodium Chloride to adjust tonicity, and Sulfuric Acid to adjust the pH to 4.0 (3.3 to 4.5).

Note: The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.

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



**SDS: XOPENEX® (levalbuterol hydrochloride)
Inhalation Solution**

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:

See section 2 and 11.

Medical Conditions Aggravated by Exposure:

Levalbuterol HCl is a potent potent bronchodilator. Medical conditions aggravated by exposure: cardiovascular system conditions, vascular smooth muscle disorders, convulsive disorders, hyperthyroidism, diabetes mellitus. Treat symptomatically and supportively. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package or prescribing information for potential drug-drug interactions.

Notes to Physician:

Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:

Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.

Unsuitable Extinguishing Media:

Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:

No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, hydrogen chloride and other chlorine-containing compounds.

Flammability/Explosivity:

No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.

Other Specific Hazards:

Not determined.

Special Protective Equipment/Precautions for Firefighters:

Wear self-contained breathing apparatus and full and protective gear. Decontaminate all equipment after use.

6. Accidental Release Measures

Personal Precautions:

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment:

If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe mist/vapors/spray.



**SDS: XOPENEX® (levalbuterol hydrochloride)
Inhalation Solution**

Methods for Cleaning Up: DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9).

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: Store at 20°– 25°C (68°– 77°F) away from incompatible materials. Keep out of reach of children. Avoid direct sunlight. Avoid extreme temperatures.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Levalbuterol Hydrochloride	Sunovion OEL: 1 µg/m, 8 Hour TWA
Sulfuric Acid	ACGIH TLV: 0.2 mg/m ³ TWA OSHA PEL: 1 mg/m ³ TWA OSHA STEL: 3 mg/m ³ TWA

Note: Wash hands, face and other potentially exposed areas immediately in the event of physical contact. Dispose of broken vials/syringes in a sharps container.

Engineering Controls: None required for normal handling of packaged product. If vials are crushed or broken: Control exposures to below the OEL of active pharmaceutical ingredient. Otherwise, selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Open handling should not be performed when handling potent substances, or substances of unknown toxicity. Material should be handled inside a closed process, ventilated enclosure, isolator or device of equivalent or better control that is suitable for dusts and/or aerosols.



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Respiratory Protection:	None required for normal handling of packaged product. 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:	None required for the normal handling of packaged product. Safety glasses with side shields are recommended. 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:	None required for the normal handling of packaged product. 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:	None required for the normal handling of packaged product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Clear, colorless liquid.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	4.0.
Melting Point:	Not applicable.
Freezing Point:	Not applicable.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
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):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.



SDS: XOPENEX® (levalbuterol hydrochloride)
Inhalation Solution

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	Not expected to occur.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Avoid extreme temperatures.
Incompatible Materials:	Strong oxidizing agents, strong acids and strong bases.
Hazardous Decomposition Products:	No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May be absorbed by inhalation.

Ingestion: No data available

Skin Contact: No data available

Eye Contact: No data available

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:

Hives, itching, bronchospasm, and anaphylaxis have been reported. Syncope and hypotension may occur. Cardiac arrest, basilar artery ischemia, severe shock and death may occur rarely.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Levalbuterol HCl	Rat	Oral	LD ₅₀	2,000 – 3,000 mg/kg
Levalbuterol HCl	Rat	Intravenous	LD ₅₀	50 – 75 mg/kg
Sodium Chloride	Rat	Oral	LD ₅₀	3,000 mg/kg
Sodium Chloride	Mouse	Oral	LD ₅₀	4,000 mg/kg
Sodium Chloride	Rat	Inhalation	LC ₅₀	>42 g/m ³ (1-hr)
Sodium Chloride	Rabbit	Dermal	LD ₅₀	>10,000 mg/kg
Sulfuric Acid	Rat	Oral	LD ₅₀	2,140 mg/kg
Sulfuric Acid	Rat	Inhalation	LC ₅₀	510 mg/m ³
Sulfuric Acid	Mouse	Inhalation	LC ₅₀	320 mg/m ³

Corrosivity: Sulfuric acid is a corrosive substance and can cause severe skin/eye burns.

Dermal Irritation: No data available.

Eye Irritation: No data available.



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Sensitization:	No data available.
STOT-repeated exposure/ Repeat dose toxicity:	Inhalation studies of up to 3 months' duration were conducted with Levalbuterol using rats and dogs. No local signs of intolerance in respiratory tissue were seen at doses up to 6 and 0.28 mg/kg/day, respectively. These doses are considered NOAELs. Additional study details were not identified.
Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	Based on clinical use, possible target organs include the central and peripheral nervous systems and the cardiovascular system.
Reproductive Effects:	No studies identified for Levalbuterol HCl. However, racemic albuterol sulfate did not impair fertility in rats at doses up to 50 mg/kg/day (route not specified).
Developmental Toxicity:	Levalbuterol HCl was not teratogenic in rabbits at oral doses up to 25 mg/kg/day.
Genotoxicity:	Levalbuterol HCl was negative in the Ames bacterial mutagenicity assay, a forward mutation assay test in mammalian cells, and an in vivo mouse micronucleus test.
Carcinogenicity:	No studies identified for levalbuterol HCl. However, racemic albuterol sulfate given orally (diet) to rabbits caused benign tumors of the female reproductive organs starting at 2 mg/kg/day. In contrast, dietary studies of racemic albuterol sulfate in mice (18 months) and hamsters (22 months) were negative at up to 50 mg/kg/day. Overall, these data suggest that albuterol, and levalbuterol, are not likely to be carcinogenic. Levalbuterol is not listed by NTP, IARC, ACGIH or OSHA as a carcinogen. Sulfuric acid is labeled as a group 1 (carcinogenic to humans) by IARC, and as known to be a human carcinogen by NTP.
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.
Mutagenicity:	No data available.
Aspiration Hazard:	No data available.



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12. Ecological Information

Ecotoxicity

Aquatic:

Compound	Species	Test Type	Dose
Sodium Chloride	Fish (various species)	EC ₅₀ /96h	>4,700 mg/L
Sodium Chloride	Daphnia magna	EC ₅₀ /48h	340 – 1,000 mg/L
Sulfuric Acid	Brachydanio rerio (fresh water fish)	LC ₅₀ /24h	82 mg/L
Sulfuric Acid	Shrimp	LC ₅₀ /48h	80 – 90 mg/L
Sulfuric Acid	Carassius auratus (fresh water fish)	LC ₅₀ /96h	134 mg/L
Sulfuric Acid	Daphnia magna	LC ₅₀ /48h	>914 mg/L
Sulfuric Acid	Oncorhynchus mykiss (rainbow trout)	LC ₅₀ /48h	>952 mg/kg

Terrestrial: No data available.

Persistence and Degradability: Racemic albuterol is not readily biodegradable.

Bioaccumulative Potential: Racemic albuterol is not expected to bioaccumulate.

Mobility in Soil: Racemic albuterol is immobile in soil.

Mobility in Environment: No data available.

Other Adverse Effects: No data available.

Note: Ecological characteristics of this product/mixture were not available. The ecology data listed above are for specific ingredients, where applicable. Releases to the environment should be avoided.

13. Disposal Considerations

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

14. Transport Information

Transport: Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.

UN Number: Not applicable.

UN Proper Shipping Name: Not applicable.

Transport Hazard Class(es): Not applicable.

Packing Group: Not applicable.

Department of Transportation: Not regulated as a hazardous material.

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



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**International Maritime Dangerous
Good (IMDG):**

Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

**Toxic Substance Control Act
(TSCA):**

Exempt.

**CERCLA Hazardous Substance
and Reportable Quantity:**

Not listed.

**SARA 313:
SARA 302:**

Not listed.
Not listed.

State Regulations

Massachusetts:

Not listed.

New Jersey:

Not listed.

Pennsylvania:

Not listed.

California Proposition 65:

Not listed.

16. Other Information

**Full text of R phrases
and EU Classifications:**

C - Corrosive. T - Toxic. R22 - Harmful if swallowed. R35 - Causes severe burns. R48/23 - Danger of serious damage to health by prolonged exposure by inhalation.

**Full text of H phrases, P
phrases and GHS classification:**

ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. SC1 - Skin corrosion Category 1. H314 - Causes severe skin burns and eye damage. E11 - Eye corrosion Category 1. H318 - Causes serious eye damage. STOT-R1 – Specific Target Organ Toxicity Following Repeat Exposure Category 1. H372 - Causes damage to the cardiovascular and respiratory systems through prolonged or repeated exposure.

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