Cold Harbor
5/23/2021

TABLE OF CONTENTS

Baxter

SAFETY DATA SHEET

Issuing Date: 01/29/2015 **Revision Date:** 05/08/2017

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

Product Identifier
MSDS Number: 1214283
Product Name: 0.9% Sodium Chloride Irrigation Solution

Other means of identification
Product Code(s): 2F7122, 2F7123, 2F7124, 2F7125
Synonyms: None

Recommended use of the chemical and restrictions on use
Product Use: Pharmaceutical.
Product Type: Irrigating solution
Uses advised against No information available

Details of the supplier of the safety data sheet
BAXTER HEALTHCARE CORPORATION
1 BAXTER PARKWAY
DEERFIELD, ILLINOIS 60015
US: (800) 933-0303
Canada: (855)-584-1368

Emergency telephone number
Rocky Mountain Poison and Drug Center: USA (888) 990-0996
OUTSIDE USA (303) 389-1422
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status
This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label Elements

Emergency Overview

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

Hazards not otherwise classified (HNOC)
Other Information

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS-No	Weight-%
Sodium Chloride	7647-14-5	<1
Water	7732-18-5	>99

4. FIRST AID MEASURES

First Aid Measures

General Advice Treat symptomatically and supportively.

Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

Skin contact: Wash contaminated skin with soap and water. Get medical attention if irritation develops.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms occur.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Most important symptoms and effects, both acute and delayed
No information available.

Indication of any immediate medical attention and special treatment needed
Treat symptomatically.

5. FIRE-FIGHTING MEASURES

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

Specific hazards arising from the chemical
No information available.

Special protective equipment for firefighters
Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
Follow all fire fighting procedures (Section 5). Use personal protection recommended in Section 8.

Environmental Precautions
See Section 12 for environmental precautions.

Methods and material for containment and cleaning up
Methods for Containment:
If emergency personnel are unavailable, contain spilled material.
Methods for cleaning up
For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container 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 container for disposal.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Technical measures/precautions: Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature 25 °C (77 °F). Avoid excessive heat.

Incompatible materials No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

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

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Sodium Chloride 7647-14-5	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Appropriate engineering controls

Engineering Measures No special containment is required.

Individual protection measures, such as personal protective equipment

Eye protection Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

Hand protection Not required.

Skin and body protection Not required.

Respiratory protection No personal respiratory protective equipment normally required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state: Liquid
Appearance: Aqueous solution
Color: Colorless. Clear
Odor: Not available
Odor Threshold: No information available
pH: 4.5-7.0
Melting point / melting range: Not available
Boiling point / boiling range: Not available
Flash point: Not determined
Evaporation rate: Not available
Flammability (solid, gas): No information available
Flammable limits in air-upper (%): Not available.
Flammable limits in air-lower (%): Not available.
Vapor pressure: Not available
Vapor Density: No information available
Density: Not available
Solubility: Not available
Partition coefficient (n-octanol/water): Not available

Autoignition temperature: Not available.
Decomposition Temperature: No information available
Viscosity: Not available
Explosive Properties: No information available
Oxidizing Properties: No information available

Other Information

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
Do not freeze.

Incompatible materials
None known

Hazardous Decomposition Products
No data available

11. TOXICOLOGICAL INFORMATION

Component	Inhalation LC50	Dermal LD50	Oral LD50
Sodium Chloride 7647-14-5	42 g/m³ 1 h (Rat)	> 10 g/kg (Rabbit)	= 3 g/kg (Rat)
Water 7732-18-5	-	-	> 90 mL/kg (Rat)

Information on likely routes of exposure

Inhalation: Inhalation not likely under normal use conditions.

Eye contact: Not expected to cause eye irritation.

Skin contact: Not expected to cause skin irritation.

Ingestion: Not expected to be hazardous by ingestion.

Information on Toxicological Effects

Symptoms: No information available.

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

Irritation: Not classified.

Corrosivity: Not classified.

Sensitization: Not classified.

Mutagenic effects: Not classified.

Carcinogenic effects: Not classified.

Component	ACGIH	IARC	NTP	OSHA
Sodium Chloride 7647-14-5	-	-	-	-
Water 7732-18-5	-	-	-	-

Reproductive toxicity: Not classified.

STOT - single exposure: Not classified.

STOT - repeated exposure: Not classified.

Aspiration Hazard: Not classified.

Numerical measures of toxicity - Product Information

12. ECOLOGICAL INFORMATION

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Sodium Chloride 7647-14-5	1000 mg/L EC50 48 h 340.7 - 469.2 mg/L EC50 48 h	4747 - 7824 mg/L LC50 Oncorhynchus mykiss 96 h 12946 mg/L LC50 Lepomis macrochirus 96 h 6020 - 7070 mg/L LC50 Pimephales promelas 96 h 6420 - 6700 mg/L LC50 Pimephales promelas 96 h 5560 - 6080 mg/L LC50 Lepomis macrochirus 96 h 7050 mg/L LC50 Pimephales promelas 96 h	None.	None.
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity
No information available
0 % of the mixture consists of components(s) of unknown hazards to the aquatic environment

Persistence and degradability
No information available.

Bioaccumulative potential
No information available

Mobility in soil
No information available.

Other adverse effects
No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues/unused products In accordance with local and national regulations

Contaminated Packaging In accordance with local and national regulations.

14. TRANSPORT INFORMATION

DOT Not regulated

15. REGULATORY INFORMATION

U.S. Regulations:
TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Component	Weight-%	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Sodium Chloride 7647-14-5	<1	Not Listed	Not Listed	Not Listed	Not Listed
Water 7732-18-5	>99	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop. 65	Minnesota Right-To -Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Sodium Chloride 7647-14-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water 7732-18-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product complies with DSL

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):
New GHS format. Changes to Section 1.

Additional information:

Not Available.

Prepared by Baxter Research & Development
Issuing Date: 01/29/2015
Revision Date: 05/08/2017

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.

End of Safety Data Sheet

B. Braun Medical Inc.
824 12th Avenue
Bethlehem, PA 18018

Telephone: (610) 691-5400
Fax: (610) 691-2202

Dear Valued Customer:

You requested a safety data sheet for Dextrose Injections and Dextrose and Sodium Chloride Injections distributed by B. Braun. The product codes are as follows:

Dextrose and Sodium Chloride Injections		
Reference Number	**Container Type**	**Size (mL)**
L6050	EXCEL®	1000
L6080-00	EXCEL	1000
L6081-00	EXCEL	500
L6100	EXCEL	1000
L6101	EXCEL	500
L6120	EXCEL	1000
L6121	EXCEL	500
L6122	EXCEL	250
L6140	EXCEL	1000
L6141	EXCEL	500
L6160	EXCEL	1000
L6161	EXCEL	500
L6162	EXCEL	250
L6200	EXCEL	1000
L6232	EXCEL	250

Dextrose Injections		
Reference Number	**Container Type**	**Size (mL)**
L5100	EXCEL®	1000
L5101	EXCEL	500
L5102	EXCEL	250
S5104-5264	PAB®	100 fill in 150mL
S5104-5384	PAB	50 fill in 100mL
S5104-5410	PAB	25 fill in 100mL
L5200	EXCEL	1000
L5201	EXCEL	500
L5202	EXCEL	250

We are pleased to inform you that this particular B. Braun product does not contain any hazardous chemicals or harmful physical agents as defined by the Hazard Communication Standard (29 CFR1910.1200).

This information is provided independently of any sale of product and is not intended to constitute product performance information. No express or implied warranty of any kind is made with respect to the product, underlying data or the information contained herein. Further, this information is not intended to provide specialist advice or instructions regarding the products and services sold by B. Braun.

If further assistance is needed, please call our Clinical and Technical Support department at (800) 854-6851.

Sincerely,

Clinical & Technical Support

Baxter

SAFETY DATA SHEET

Issuing Date: 02/27/2015 **Revision Date:** 02/27/2015

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

Product Identifier
MSDS Number: 1266502
Product Name: 0.9% Sodium Chloride Injection, USP

Other means of identification
Product Codes: 1A1322, 1A1323, 2B0042, 2B0043, 2B1300, 2B1301, 2B1302, 2B1306, 2B1307, 2B1308, 2B1309, 2B1321, 2B1322Q, 2B1323Q, 2B1324, 4R2180T, 4R2182, 4R2310, 4R2312, 6E1322, 6E1323, 6E1324, FE1323, FE1324D
Synonyms: None

Recommended use of the chemical and restrictions on use
Product Use: Pharmaceutical.
Product Type: Injectable solution
Uses advised against: No information available

Details of the supplier of the safety data sheet
BAXTER HEALTHCARE CORPORATION
DEERFIELD, ILLINOIS 60015
(800) 422-9837 or (224) 948-4770

Emergency telephone number
Rocky Mountain Poison and Drug Center: USA (888) 990-0996
OUTSIDE USA (303) 389-1422
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status
This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label Elements

Emergency Overview

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

Hazards not otherwise classified (HNOC)
Other Information
Unknown Acute Toxicity 0% of the mixture consists of ingredient(s) of unknown toxicity

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS-No	Weight %
Sodium Chloride	7647-14-5	<1

Water	7732-18-5	>99

4. FIRST AID MEASURES

First Aid Measures

General Advice: Treat symptomatically and supportively.

Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

Skin contact: Wash contaminated skin with soap and water. Get medical attention if irritation develops.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Most important symptoms and effects, both acute and delayed
No information available.

Indication of any immediate medical attention and special treatment needed
Treat symptomatically. See patient package insert in shipping carton for complete information.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
Water.

Specific hazards arising from the chemical
No information available.

Special protective equipment for firefighters:
Fire fighters should wear proper protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental Precautions
See Section 12 for environmental precautions.

Methods and material for containment and cleaning up
Methods for Containment:
If emergency personnel are unavailable, contain spilled material.
Methods for cleaning up:
For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container 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 container for disposal.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Technical measures/precautions: None

Conditions for safe storage, including any incompatibilities

Technical measures/conditions: Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature 25 °C (77 °F). Avoid excessive heat.

Incompatible products: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

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

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Sodium Chloride 7647-14-5	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Appropriate engineering controls

Engineering measures: No special containment is required.

Individual protection measures, such as personal protective equipment

Eye protection: Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

Hand protection: Not required.

Skin and body protection: Not required.

Respiratory protection: No personal respiratory protective equipment normally required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state: Liquid
Appearance: Aqueous solution
Color: Clear, Colorless.
Odor: No information available.
Odor Threshold: No information available.
pH: 4.5-7.0
Melting point/range: No information available.
Boiling point/range: No information available.
Flash point: No information available.
Evaporation rate: No information available.
Flammability (solid, gas): No information available.
Flammable limits in air-upper (%): No information available.
Flammable limits in air-lower (%): No information available.
Vapor pressure: No information available.
Vapor Density: No information available.
Density: No information available.
Solubility: No information available.

Partition coefficient (n-octanol/water):	No information available.
Autoignition temperature:	No information available.
Decomposition Temperature:	No information available.
Viscosity:	No information available.
Explosive Properties:	No information available.
Oxidizing Properties:	No information available.

Other Information

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
Do not freeze.

Incompatible materials
None known

Hazardous Decomposition Products
No data available.

11. TOXICOLOGICAL INFORMATION

Component	LC50 Inhalation	LD50 Dermal	LD50 Oral
Sodium Chloride 7647-14-5	> 42 g/m³ (Rat) 1 h	-	= 3 g/kg (Rat)
Water 7732-18-5	-	-	-

Information on likely routes of exposure

Inhalation: Inhalation not likely under normal use conditions.

Eye contact: Not expected to cause eye irritation.

Skin contact: Not expected to cause skin irritation.

Ingestion: Not expected to be hazardous by ingestion.

Information on Toxicological Effects

Symptoms: No information available.

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

Irritation: Not classified.

Corrosivity: Not classified.

Sensitization: Not classified.

Mutagenic effects: No mutagenicity studies have been conducted.

Carcinogenic effects: Not classified

Component	ACGIH	IARC	NTP	OSHA
Sodium Chloride 7647-14-5	-	-	-	-
Water 7732-18-5	-	-	-	-

Reproductive toxicity: Reproductive studies have not been conducted on the product itself.

STOT - single exposure: Not classified.

STOT - repeated exposure: Not classified.

Aspiration Hazard: Not classified.

Numerical measures of toxicity - Product Information

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

12. ECOLOGICAL INFORMATION

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Sodium Chloride 7647-14-5	340.7 - 469.2 mg/L EC50 48 h 1000 mg/L EC50 48 h	5560 - 6080 mg/L LC50 Lepomis macrochirus 96 h 12946 mg/L LC50 Lepomis macrochirus 96 h 6020 - 7070 mg/L LC50 Pimephales promelas 96 h 7050 mg/L LC50 Pimephales promelas 96 h 6420 - 6700 mg/L LC50 Pimephales promelas 96 h 4747 - 7824 mg/L LC50 Oncorhynchus mykiss 96 h	None.	None.
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity
No information available
0% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Persistence and degradability
No information available.

Bioaccumulative potential

No information available

Mobility in soil
No information available.

Other adverse effects
No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues / unused products: In accordance with local and national regulations.
Contaminated Packaging: In accordance with local and national regulations.

14. TRANSPORT INFORMATION

DOT Not regulated

15. REGULATORY INFORMATION

U.S. Regulations:
TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Sodium Chloride 7647-14-5	<1	Not Listed	Not Listed	Not Listed	Not Listed
Water 7732-18-5	>99	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop. 65	Minnesota Right-To -Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Sodium Chloride 7647-14-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water 7732-18-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product complies with DSL

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):
New GHS format.

Additional information:
Not Available.

Prepared by: Baxter Research & Development
Issuing Date: 02/27/2015
Revision Date: 02/27/2015

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.

End of Safety Data Sheet

Bausch & Lomb

Advanced Eye Relief™ Dry Eye Environmental Lubricant Eye Drops

MATERIAL SAFETY DATA SHEET

Effective Date: 3/20/07 Supersedes: 2/24/06

Section 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Advanced Eye Relief™ Dry Eye Environmental Lubricant Eye Drops
Product Code(s): 622211
Manufacturer: Bausch & Lomb, Incorporated
Address: 1400 N. Goodman Street
Rochester, New York 14609

For Information: 1-800-553-5340
For Emergency: 1-800-535-5053

Section 2: COMPOSITION / INFORMATION ON INGREDIENTS

			OCCUPATIONAL EXPOSURE LIMITS / GUIDELINES										
			OSHA PEL		ACGIH TLV		NIOSH REL		IRELAND		HSE		
CAS #	COMPONENT NAME	% W/W	TWA	STEL	TWA	STEL	TWA	STEL	TWA	STEL	TWA	STEL	UNITS
7647-14-5	Sodium Chloride	<2.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
7447-40-7	Potassium Chloride	<2.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
1303-96-4	Sodium Borate	<2.0	NE	NE	2	6	5	NE	5	NE	5	NE	MG/M3
10043-35-3	Boric Acid	<2.0	NE	NE	2	6	NE	NE	NE	NE	NE	NE	MG/M3
56-81-5	Glycerine	1	15*5**	NE	10	NE	NE	NE	10	NE	10	NE	MG/M3
8001-54-5	Benzalkonium Chloride (50%)	0.01	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
139-33-3	Edetate Disodium	<0.1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
7732-18-5	Purified water	Balance											
TOTAL		100***											

N/E: Not Established
N/A: Not Applicable
ACGIH: American Conference of Governmental Industrial Hygienists
NIOSH: National Institute for Occupational Safety & Health
OSHA: Occupational Safety & Health Administration
PPM: Parts Per Million MG/M3: Milligrams Per Cubic Meter
TWA: 8-Hour Time-Weighted Average
STEL: Short-Term Exposure Limit
C: Ceiling Limit
REL: Recommended Exposure Limit

* Total Mist
** Respirable Mist
*** pH balanced with sodium hydroxide and/or hydrochloric acid

Section 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Clear liquid with no odor. This product is intended for use as an eye drop. If you are allergic to any ingredient in this product, DO NOT USE.

Section 3: HAZARDS IDENTIFICATION (cont.)

PRECAUTIONS:

If any discomfort develops, immediately discontinue use of this product. If discomfort persists, contact your eye care professional. Use in accordance with product literature.

If you are allergic to any ingredient in this product, DO NOT USE.

POTENTIAL HEALTH EFFECTS

EYE:

Non-irritating to the eyes when used as directed.

SKIN:

Non-irritating to skin or mucous membranes when used as directed.

INGESTION:

Small amounts (a tablespoonful) swallowed are not likely to cause injury; swallowing amounts larger than that may cause gastrointestinal irritation.

INHALATION:

No hazard when used as directed.

CHRONIC HEALTH EFFECTS

No known chronic hazards.

CARCINOGENICITY:

NTP: No ingredients listed.
IARC: No ingredients listed.
OSHA: No ingredients listed.

Section 4: FIRST AID MEASURES

EYES:

If discomfort or irritation develops, immediately discontinue product use and contact your eye care professional.

SKIN:

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

Section 4: FIRST AID MEASURES (cont.)

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.

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 if cough or other symptoms develop.

Section 5: FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES:

Flash Point: Non-Combustible

Method: NA

EXTINGUISHING MEDIA:

Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

HAZARDOUS COMBUSTION PRODUCTS:

None identified.

SPECIAL FIRE FIGHTING INSTRUCTIONS:

As in any fire, wear self-contained breathing apparatus and full protective gear.

Section 6: ACCIDENTAL RELEASE MEASURES

General Information:

Contain spill and absorb with a suitable inert material, then place in a chemical waste container. Dispose of in accordance with Section 13.

Section 7: HANDLING AND STORAGE

HANDLING:

No special handling is required. Use in accordance with product literature.

STORAGE:

Store at room temperature to maintain product integrity.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATORY PROTECTION:

No special controls or personal protection required under conditions of intended use.

SKIN PROTECTION:

No special controls or personal protection required under conditions of intended use.

EYE PROTECTION:

No special controls or personal protection required under conditions of intended use.

ADDITIONAL PROTECTIVE CLOTHING & EQUIPMENT:

NA

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES:

Appearance / Physical State:	Clear, Water-Like
Odor:	Odorless

CHEMICAL PROPERTIES:

Boiling Point:	Not Determined	**Melting Point:**	Not Applicable
Vapor Pressure:	Not Determined	**Vapor Density:**	Not Determined
Solubility In Water:	Highly Soluble	**Specific Gravity (H2O = 1):**	1
pH:	6.0-7.8	**Freezing Point:**	Not Determined

Molecular Weight: Mixture, Not Applicable

Section 10: STABILITY AND REACTIVITY

GENERAL:

Stable under normal conditions.

INCOMPATIBLE MATERIALS AND CONDITIONS TO AVOID:

None.

HAZARDOUS POLYMERIZATION:

Will not occur.

HAZARDOUS DECOMPOSITION:

None identified.

Section 11: TOXICOLOGICAL INFORMATION

RTECS No.: **ED4550000**

Boric Acid

Toxicity Data:	ORL-RAT	LD50: 2660 MG/KG
	ORL-HUMAN	LDLO: 429 MG/KG
Irritation Data:	SKN-HUMAN	15 MG/3D (MILD)

RTECS No.: **SC7310000**

Sodium Borate

Toxicity Data:	ORL-MOUSE	LD50: 3250 MG/KG

RTECS No.: **VZ4725000**

Sodium Chloride

Toxicity Data:	ORL-RAT	LD50: 3 GM/KG
	ORL-MOUSE	LD50: 4 GM/KG

RTECS No.: **TS8050000**

Potassium Chloride

Toxicity Data:	ORL-RAT	LD50: 2600 MG/KG

RTECS No.: **MA8050000**

Glycerine

Toxicity Data:	ORL-RAT	LD50: 12600 MG/KG

RTECS No.: **BO3150000**

Zephiran Chloride

Toxicity Data:	ORL-RAT	LD50: 240 MG/KG

RTECS No.: **AH4375000**

Edetate Disodium

Toxicity Data:	ORL-RAT	LD50: 2 G/KG

NOTE: Only selected Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information.

Section 12: ECOLOGICAL INFORMATION

No data available on the environmental impact of this product.

Section 13: DISPOSAL CONSIDERATIONS

All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Section 14: TRANSPORT INFORMATION

	US DOT	IATA	IMO	RID/ADR	Canadian DG
Shipping Name:	Not Regulated	Not Regulated	No Information Available	No Information Available	No Information Available
Hazard Class:	NA	NA			
UN Number:	NA	NA			
Package Group:	NA	NA			

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR, Part 173) are not applicable to this product.

Section 15: REGULATORY INFORMATION

OSHA HAZARD COMMUNICATION STANDARD (29 CFR 1910.1200):

Advanced Eye Relief™ Dry Eye Environmental Lubricant Eye Drops is considered non-hazardous under the Occupational Safety & Health Administration Hazard Communication Standard.

TOXIC SUBSTANCE CONTROL ACT (TSCA):

All ingredients are listed on the TSCA inventory.

SARA TITLE III (Superfund Amendments and Reauthorization Act):

SECTION 302 (Extremely Hazardous Substances): No Components Listed
SECTION 311, 312 (Hazard Categories): NA
SECTION 313 (Toxic Chemicals): No Components Listed

CALIFORNIA PROPOSITION 65:

This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels that would require a warning under the statute.

Section 16: OTHER INFORMATION

To the best of our knowledge, the information contained herein is accurate. However, neither Bausch & Lomb Incorporated 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 Incorporated or any of its subsidiaries be liable for any special, incidental or consequential damages.

nephron pharmaceuticals corporation

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, 0.042%* and 0.021%* *potency expressed as albuterol, 1.5mg*(0.042%) or 0.75mg (0.021%) 3mg 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, 0.042% or 0.021% 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: COMPOSITON / INFORMATION ON INGREDIENTS

NAME:	Albuterol Sulfate
CAS#:	51022-70-9
% w/v	0.042% or 0.021% albuterol sulfate
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: Protect from light and excessive heat 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 and odorless.
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 albuterol sulfate, the active ingredient in Albuterol Sulfate Inhalation Solution, 0.042% or 0.021%.

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, 0.5 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/m3 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, difficultybreat hing 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, 0.042% or
0.021% 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, 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, 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.

ENVIRONMENTAL TEST RESULTS:

SECTION 13: DISPOSAL CONSIDERATIONS

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

SECTION 14: TRANSPORT INFORMATION

Component 1 or Formulation 1: Albuterol Sulfate Inhalation Solution 0.042% or 0.021%
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: 02-06-2015

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.

SAFETY DATA SHEET

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

Product Identifier

Material Name: Bacteriostatic Water for Injection, USP (Hospira Inc.)

Trade Name: Bacteriostatic Water for Injection, USP
Chemical Family: Not determined

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards No data available
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	%

3. COMPOSITION / INFORMATION ON INGREDIENTS

BENZYL ALCOHOL	100-51-6	202-859-9	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	1.1

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 eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Rinse with 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: Move to fresh air If discomfort occurs, get medical attention.

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

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

6. ACCIDENTAL RELEASE MEASURES

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. Do not refrigerate.
Incompatible Materials: None known
Specific end use(s): Pharmaceutical product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

BENZYL ALCOHOL

Pfizer OEL TWA-8 Hr:	10 ppm
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

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: Wear impervious gloves (e.g. Nitrile, etc.) if skin contact is possible. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses as minimum protection. (Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: 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.)

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:	Liquid	**Color:**	Colourless
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility: No data available
Water Solubility: Soluble
pH: 4.5-7.0
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
BENZYL ALCOHOL
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: None
Conditions to Avoid: None known
Incompatible Materials: None known
Hazardous Decomposition Products: None known

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause eye irritation (based on components) .

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

BENZYL ALCOHOL
Rat Oral LD 50 1230 mg/kg
Mouse Oral LD 50 1360mg/kg
Rabbit Dermal LD 50 2gm/kg

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

12. ECOLOGICAL INFORMATION

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

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

BENZYL ALCOHOL
Fathead Minnow NPDES LC-50 96 Hours 460 - 770 mg/L
Bluegill NPDES LC-50 96 Hours 10 mg/L
Daphnia Magna (Water Flea) Surrogate ErC50 48 Hours 23 - 400 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

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

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

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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

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

Revision date: 25-Jul-2016
Product Stewardship Hazard Communication

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

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

End of Safety Data Sheet

SAFETY DATA SHEET

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

Product Identifier

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

Trade Name: Not established
Chemical Family: Cephalosporin antibiotic

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

Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

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

Precautionary Statements:

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

Other Hazards

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

Note:

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Ceftriaxone sodium	74578-69-1	277-930-0	Resp. Sens. 1 (H334) Skin Sens. 1 (H317)	100

Additional Information:

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

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

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

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

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

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

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

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

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid breathing dust. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Ceftriaxone sodium

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

Exposure Controls

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

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

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

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

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

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

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Ceftriaxone sodium
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

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

Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available
Polymerization:	Will not occur

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

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

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

Ceftriaxone sodium

Rat Oral LD50 > 10 g/kg

Rat Subcutaneous LD50 > 5g/kg

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

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

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

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

Ceftriaxone sodium

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

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

Ceftriaxone sodium

11. TOXICOLOGICAL INFORMATION

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

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

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

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

15. REGULATORY INFORMATION

Ceftriaxone sodium

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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

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

Data Sources:	Publicly available toxicity information.
Reasons for Revision:	New data sheet.
Revision date:	28-Oct-2016
Prepared by:	Product Stewardship Hazard Communication Pfizer Global Environment, Health, and Safety Operations

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

End of Safety Data Sheet

APOTEX
Innovating for patient affordability

Safety Data Sheet

Section 1. Identification

Common/Trade name : **Cefazolin for Injection USP**

Recommended use : Dosage form
Therapeutic category: Antibacterial.

This Safety Data Sheet has been provided to inform workers of the safety, health and environmental information associated with this product. It is to be used by people handling the material within the workplace only. It is not meant for patients taking the medication. Patients should consult with their physician, pharmacist or the information provided on the label or on the insert.

Recommended restrictions : No other uses are advised.

Supplier :

Canada
Apotex Inc.
150 Signet Drive
Toronto, Ontario
M9L 1T9
416-749-9300

U.S.
Apotex Corp.
2400 N. Commerce Parkway
Suite 400
Weston, FLA 33326
Telephone: (954)384-8007
Toll Free: 1-800-706-5575

Emergency phone : United States/Canada (Chemtrec) 1-800-424-9300 or
+1 703-527-3887 (24 hours)
For general information call:
1-(416)-749-9300 ext. 8483 (8 AM-4 PM)

Section 2. Hazards Identification

Classification of the substance or mixture : As per 29 CFR 1910.1200 (b)(6) and according to Article 1, item 5 a) of CLP Regulation (EC) 1272/2008, medicinal products (drugs) when it is in the solid, final form for direct administration to the patient or are packaged by the manufacturer for sale to consumers in a retail establishment are exempt from the requirements of classification, labels and SDS's.

GHS label elements : Exempt from requirements.

Hazards not otherwise classified : Exempt from requirements.

Section 3. Composition/Information on Ingredients

Name	CAS #	% (w/w)
Cefazolin sodium	27164-46-1	100

Specific chemical identity and/or percentage of composition has been withheld as a trade secret.

Chemical name : 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[[(5-methyl-1,3,4-thiadiazol-2-yl)thio]methyl]-8-oxo-7-[[1H-tetrazol-1-yl)acetyl]amino]-(6R-trans)

Synonyms : Brand name: Ancef

Chemical family : Cephalosporin

Molecular weight : 476.52 g/mole

Chemical formula : $C_{14}H_{13}N_8O_4S_3.Na$

Section 4. First Aid Measures

Eye contact : Flush with copious quantities of water. If irritation persists, obtain medical advice.

Skin contact : Flush with copious amounts of water. Seek medical attention if irritation persist.

Inhalation : Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.

Ingestion : Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.

Potential acute and delayed health effects : Refer to Sec. 11

Section 5. Fire Fighting Measures

Specific hazard arising from the chemical : During fire, gases hazardous to health may be formed.

Suitable extinguishing media and special protective equipment for firefighters : Extinguisher media: water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Methods and materials for containment and cleaning up : Contain and clean up spillage and place into an appropriate labeled waste disposal container. Avoid generating dust or aerosols. Wash spill surface using appropriate cleaning solutions. Should clothing be contaminated, wash before reuse.

Protective equipment and personal precautions : Keep unnecessary personnel away. Wear appropriate personal protective equipment.

Section 7. Handling and Storage

Precautions for safe handling : Avoid inhalation, skin and eye contact.

Conditions for safe storage : Before reconstitution protect from light and store 20°C to 25°C (68° to 77°F).

Section 8. Exposure Controls/Personal Protection

Engineering Controls : General room ventilation. Local exhaust ventilation and/or process enclosures where applicable. Fume hoods where available. Additional respiratory protection is not required when working in a fume hood.

Personal Protection : Skin: Lab coat

Respiratory: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. If the physical state of the finished product is altered by crushing, grinding or breakage or for spill cleaning, an approved NIOSH respirator may be required.

Hand: Nitrile gloves

Eye: Safety glasses

Occupational exposure limits : Not established.

Section 9. Physical and Chemical Properties

Physical state and appearance : Sterile crystalline powder.

pH :	Between 4.0 and 6.0 (10% w/v aq. solution)	**Odor** :	Not available.
Melting point/ Freezing point :	Not available.	**Odor threshold** :	Not available.
Boiling point :	Not available.	**Conditions of instability** :	No additional remark.
Volatility :	Not available.	**Decompositon temperature** :	Not available.
Specific gravity :	Not available.	**Partition Coefficient:** :	Not available.
Evaporation rate :	Not available.	**Viscosity** :	Not available.
Vapor density :	Not available.	**Flash points** :	Not applicable.
Relative density :	Not available.	**Flammable limits** :	Not available.
Vapor pressure :	Not available.	**Autoignition temperature** :	Not available.

Flammability : Emits toxic fumes under fire conditions.

Solubility : Freely soluble in water, very slightly soluble in alcohol.

Section 10. Stability and Reactivity

Reactivity : Not available.

Chemical Stability : The product is stable. Very hygroscopic (absorbs moisture from the air).

Possibility of hazardous reactions : Not available.

Hazardous decomp. products : When heated to decomposition material emits toxic fumes.

Incompatible materials/ Conditions to avoid : Avoid exposure to light, heat and moisture.

Section 11. Toxicological Information

Information on the likely routes of exposure : Skin contact. Eye contact

Toxicity data : RTECS#: XI0390000
TDLo: 14 mg/kg/Day (intramuscular-human)
LD50: >11 gm/kg (oral-rat)
LD50:> 11gm/kg (oral-mouse)
LD50: 4 gm/kg (intramuscular-mouse)
Sensitization data: Hypersensitivity reactions have been reported with therapeutic use of cephalosporins. Cases of anaphylaxis have been reported with the use of cefazolin.

Delayed and immediate effects and also chronic effects from short and long term exposure : Possible hypersensitization, antibiotic-associated pseudomembranous colitis, and superinfections.

Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA.

Reproductive and Developmental Effects: Pregnancy Category B. In rats, doses up to 2000 mg/kg were not associated with gestational or reproductive toxicity. A slight reduction in fetal weight was found in rats given up to 800 mg/kg of cefazolin intravenously on day 7 to 17 of gestation. No developmental effect was observed in rabbits and mice after cefazolin in daily doses of 240 m/kg and 2400 mg/kg respectively.

Mutagenicity: Cefazolin was shown to be non-mutagenic in the Ames test, mouse lymphoma test, and the mouse micronucleus test.

Remark

Medical conditions aggravated by exposure: Hypersensitivity to material; active alcoholism; history of bleeding disorders; kidney function impairment; and gastrointestinal disease, especially ulcerative colitis, regional enteritis, or antibiotic-associated colitis.
Individuals sensitive to penicillins, penicillin derivatives, penicillamine, other cephalosporins, or cephamycin may be sensitive to this material also.

Symptoms related to the physical, chemical and toxicological characteristics : Possible eye, skin, gastrointestinal and/or respiratory tract irritation.
Adverse effects for cephalosporins may include black, tarry stools; chest pain; chills; cough; fever; painful or difficult urination; shortness of breath; sore throat; sores, ulcers, or white spots on lips or in mouth; swollen glands; unusual bleeding or bruising; skin itching, rash, or redness; hives; abdominal or stomach cramps, tenderness, or pain; nausea or vomiting; watery, bloody, or severe diarrhea; headache; indigestion; flatulence; unusual tiredness or weakness; loss of appetite; dizziness; and vaginal itching, infection, or discharge. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Section 12. Ecological Information

Ecotoxicity : Not available.

Persistence and degradability : Not available.

Bioaccumulative potential : Not available.

Mobility in soil : Not available.

Other adverse effects : Not available.

Section 13. Disposal Considerations

Waste Disposal : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
TDG- road Canada/U.S.			Not regulated.		
ICAO/IATA			Not regulated.		
IMDG Class			Not regulated.		

Section 15. Regulatory Information

Canada Regulations : Covered by Food & Drug Act and therefore not regulated under WHMIS

Not on the DSL list.

Other Regulations : Not available.

Section 16. Other Information

References : RTECS Database
PDR Electronic Library
Apotex Product Monograph
U.S. Pharmacopeia

Revision date: **7/11/2017**

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.

Revised: 5/23/2016

SAFETY DATA SHEET

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 (H_2O=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.

Conforms to HazCom 2012/United States

SAFETY DATA SHEET

Cyanocobalamin Injection, USP

WEST-WARD PHARMACEUTICALS

Section 1. Identification

GHS product identifier : Cyanocobalamin Injection, USP

Synonyms : Not available.

Product code : NDC 0143-9621-25 (25 x 1 mL vials), NDC 0143-9620-10 (10 x 10 mL vials), NDC 0143-9619-10 (10 x 30 mL vials)

Chemical family : Not available.

Product type : Not available.

Container information : (2 ml Vial, amps etc)
2 mL amber glass vial, 10 mL amber glass vial, 30 mL amber glass vial.

Identified uses : Cyanocobalamin is indicated for vitamin B12 deficiencies due to malabsorption which may be associated with the following conditions:
Addisonian (pernicious) anemia
Gastrointestinal pathology, dysfunction, or surgery, including gluten enteropathy or sprue, small bowel bacteria overgrowth, total or partial gastrectomy
Fish tapeworm infestation
Malignancy of pancreas or bowel
Folic acid deficiency
It may be possible to treat the underlying disease by surgical correction of anatomic lesions leading to small bowel bacterial overgrowth, expulsion of fish tapeworm, discontinuation of drugs leading to vitamin malabsorption, use of a gluten-free diet in nontropical sprue, or administration of antibiotics in tropical sprue. Such measures remove the need for long-term administration of cyanocobalamin.
Requirements of vitamin B12 in excess of normal (due to pregnancy, thyrotoxicosis, hemolytic anemia, hemorrhage, malignancy, hepatic and renal disease) can usually be met with oral supplementation.
Cyanocobalamin Injection, USP is also suitable for the vitamin B12 absorption test (Schilling test).

Supplier's details : West-Ward Pharmaceuticals Corp.
465 Industrial Way West
Eatontown NJ 07724 USA

Emergency telephone number (with hours of operation) : CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887
24/7

Section 2. Hazards identification

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

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Section 2. Hazards identification

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Hazards not otherwise classified : None known.

Hazards not otherwise classified (HNOC) : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Other means of identification : Not available.

CAS number/other identifiers

CAS number : Not applicable.

Product code : NDC 0143-9621-25 (25 x 1 mL vials), NDC 0143-9620-10 (10 x 10 mL vials), NDC 0143-9619-10 (10 x 30 mL vials)

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

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

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

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

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

Skin contact : Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Section 4. First aid measures

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

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

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments : No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

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

Unsuitable extinguishing media : None known.

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

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

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

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Section 6. Accidental release measures

Small spill : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8).

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

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

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

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

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Section 8. Exposure controls/personal protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

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

Section 9. Physical and chemical properties

Appearance

Physical state : Liquid.

Color : Clear. Red.

Odor : Not available.

Odor threshold : Not available.

pH : 4.5 to 7

Melting point : Not available.

Boiling point : Not available.

Flash point : Not available.

Evaporation rate : Not available.

Flammability (solid, gas) : Not available.

Lower and upper explosive (flammable) limits : Not available.

Vapor pressure : Not available.

Vapor density : Not available.

Relative density : Not available.

Solubility in water : Not available.

Partition coefficient: n-octanol/water : Not available.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : Not available.

Section 10. Stability and reactivity

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

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Section 10. Stability and reactivity

Incompatible materials : Not available.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

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

Irritation/Corrosion

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

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

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

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Section 11. Toxicological information

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

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

Short term exposure

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

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

Long term exposure

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

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

Potential chronic health effects

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

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

Section 12. Ecological information

Toxicity

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

Persistence and degradability

There is no data available.

Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
Benzyl alcohol	0.87	-	low

Mobility in soil

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

Section 12. Ecological information

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

Section 13. Disposal considerations

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

Section 14. Transport information

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

AERG : Not applicable.

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

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

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption**: Not determined

United States inventory (TSCA 8b): All components are listed or exempted.

Clean Water Act (CWA) 311: Sodium hydroxide; Hydrochloric acid

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

Section 15. Regulatory information

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

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

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

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

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

SARA 313

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

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

State regulations

Massachusetts : The following components are listed: Benzyl alcohol

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : The following components are listed: Benzyl alcohol

California Prop. 65

No products were found.

Section 16. Other information

History

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

Version : 1

Prepared by : KMK Regulatory Services Inc.

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

Notice to reader

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

SANOFI PASTEUR

US - OSHA SAFETY DATA SHEET

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

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

Product identifier

Product Name DAPTACEL®

Other means of identification

Product Information Single-dose vial in packages of 10 vials

Synonyms Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

Recommended use of the chemical and restrictions on use

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

Uses advised against Not available.

Details of the supplier of the safety data sheet

Supplier Address

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

Emergency telephone number

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

2. HAZARDS IDENTIFICATION

Classification

Health Hazards
Not classified.

Physical hazards
Not classified.

OSHA Regulatory Status
This product is a vaccine that is safe for consumers when used according to the label directions. Potential hazards that may occur if product is not used according to the consumer label are as follows throughout the sheet.

Label elements

Emergency Overview

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

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

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

Chemical Name	CAS No.	Weight-%
Diphtheria Toxoid Adsorbed	N/A	N/A
Tetanus Toxoid Adsorbed	N/A	N/A
Filamentous Haemagglutinin Adsorbed (FHA)	N/A	0.001
Fimbriae Types 2 and 3 Adsorbed (FIM)	N/A	0.001
Pertactin Adsorbed	N/A	0.0006
Pertussis Adsorbed	N/A	0.002
Water	7732-18-5	q.s to 100

Note: Ingredients below reportable levels are not listed.

4. FIRST AID MEASURES

First aid measures

Eye contact In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin Contact In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

Inhalation In case of inhalation, remove to fresh air. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention if needed. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Self-protection of the first aider Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms Common effects of the vaccine include the following: fussiness/irritability; inconsolable crying; decreased activity/lethargy; fever.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

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

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical

Not available.

Hazardous combustion products Not available.

Explosion data

Sensitivity to Mechanical Impact Not available.

Sensitivity to Static Discharge None known.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
Personal precautions Wear appropriate personal protective equipment (see Section 8).

Environmental precautions
Environmental precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up
Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Wipe up with absorbent material (e.g. cloth) for disposal. Area where spill occurred can be cleaned with the regular cleaning materials designated for the area.

7. HANDLING AND STORAGE

Precautions for safe handling
Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities
Storage Conditions Store at 2° to 8°C (35° to 46°F). Do not freeze.

Incompatible materials Not available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters
Exposure Guidelines This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region specific regulatory bodies.

Appropriate engineering controls
Engineering Controls Used as supplied, no special engineering controls are needed when administering the vaccine.

Individual protection measures, such as personal protective equipment
Eye/face protection In laboratory or industrial settings, safety glasses with side shields are recommended.

Skin and body protection In laboratory or industrial settings, gloves and lab coats are recommended.

Respiratory protection Used as supplied, general room ventilation is acceptable and no special respiratory protection is needed when administering the vaccine.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid		
Appearance	Cloudy suspension.	**Odor**	Not available.
Color	White.	**Odor threshold**	Not available.

Property	Values	Remarks • Method
pH	Not available.	
Melting point/freezing point	Not available.	
Boiling point / boiling range	Not available.	
Flash point	Not available.	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	Not available.	
Lower flammability limit:	Not available.	
Vapor pressure	Not available.	
Vapor density	Not available.	
Specific Gravity	Not available.	
Water solubility	Not available.	
Solubility in other solvents	Not available.	
Partition coefficient	Not available.	
Autoignition temperature	Not available.	
Decomposition temperature	Not available.	
Kinematic viscosity	Not available.	
Dynamic viscosity	Not available.	
Explosive properties	Not available.	
Oxidizing properties	Not available.	

Other Information

Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk density	Not available.

10. STABILITY AND REACTIVITY

Reactivity
Not reactive under normal conditions.

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal handling.

Hazardous polymerization Hazardous polymerization does not occur.

Conditions to avoid
Not available.

Incompatible materials
Not available.

Hazardous Decomposition Products
None under normal use conditions.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information No data available.

Inhalation No impact known or expected under normal use.

Eye contact No impact known or expected under normal use.

Skin Contact No impact known or expected under normal use.

Ingestion No impact known or expected under normal use.

Information on toxicological effects

Symptoms Common effects of the vaccine include the following: fussiness/irritability; inconsolable crying; decreased activity/lethargy; fever.

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

Skin corrosion/irritation	Not available.
Serious eye damage/eye irritation	Not available.
Irritation	Not available.
Corrosivity	Not available.
Sensitization	Not available.
Germ cell mutagenicity	DAPTACEL vaccine has not been evaluated for mutagenic potential.
Carcinogenicity	DAPTACEL vaccine has not been evaluated for carcinogenic potential.
Reproductive toxicity	Human or animal data are not available to assess vaccine-associated risks in pregnancy.
Developmental Toxicity	Not available.
Teratogenicity	Not available.
STOT - single exposure	Not classified.
STOT - repeated exposure	Not classified.
Chronic toxicity	Not available.
Subchronic toxicity	Not available.
Target Organ Effects	Not available.
Neurological effects	Not available.
Other adverse effects	Not available.
Aspiration hazard	Not available.

Numerical measures of toxicity - Product Information

12. ECOLOGICAL INFORMATION

Ecotoxicity
Not available.

Persistence and degradability
Not available.

Bioaccumulation
Not available.

Mobility
Not available.

Other adverse effects Not available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

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

Contaminated packaging Disposal should be in accordance with applicable regional, national and local laws and regulations.

US EPA Waste Number Not applicable.

California Hazardous Waste Codes Not applicable.

14. TRANSPORT INFORMATION

DOT Not regulated.

TDG Not regulated.

MEX Not regulated.

ICAO (air) Not regulated.

IATA Not regulated.

IMDG Not regulated.

RID Not regulated.

ADR Not regulated.

ADN Not regulated.

15. REGULATORY INFORMATION

US Federal Regulations

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

SARA 311/312 Hazard Categories

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

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

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355).

US State Regulations

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

U.S. State Right-to-Know Regulations
This drug is regulated by the Food and Drug Administration and is therefore exempt from State Right-to-Know Regulations.

16. OTHER INFORMATION

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

Disclaimer

Sanofi Pasteur considers that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals. Sanofi Pasteur cannot be held liable for any loss, injury or damage from contact with the product.

End of Safety Data Sheet

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Dexamethasone Sodium Phosphate Injection, USP Simplist™ 4mg/mL**
Manufacturer Name:	Fresenius Kabi Simplist™
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
SDS Creation Date:	March 18, 2016
SDS Revision Date:	March 18, 2016

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. Category 1.
Skin Sensitization. Category 1.
Acute Oral Toxicity. Category 4.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
Harmful if swallowed.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF exposed or concerned: Get medical advice/attention.
Rinse mouth.
If skin irritation or rash occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Potential Health Effects:
This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Dexamethasone Phosphate	2392-39-4	0.4 - 1 by weight	

Notes :
Non-hazardous ingredients include Water for Injection and Sodium citrate. Sodium hydroxide may be added to adjust the pH.

SECTION 4 : FIRST AID MEASURES

Eye Contact:
Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact:
Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes.
Get medical attention if irritation develops or persists.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion:
If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Sensitive to heat. Do not autoclave. Protect from freezing. Protect from light.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Colorless.

Odor:	Odorless.
Odor Threshold:	No information.
Boiling Point:	Approximately that of water, 100°C (212°F)
Melting Point:	Approximately that of water, 0°C (32°F)
Specific Gravity:	1.0045
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	7.0 - 8.5
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Protect from light and excessive heat. Do not autoclave. Do not freeze.

SECTION 11 : TOXICOLOGICAL INFORMATION

Acute Toxicity:	ACUTE EFFECTS: In the event of an overdose, no specific antidote is available. Treatment is supportive and symptomatic.
Dexamethasone Phosphate :	
Acute Toxicity:	LD50: IV Female Mouse 794 mg/kg
Acute Effects:	In the event of an overdose, no specific antidote is available. Treatment is supportive and symptomatic.
Chronic Effects:	Prolonged exposure may result in subcasular cataracts, glaucoma, hypertension, salt and water retention, and hypokalemia.
Dexamethasone Phosphate :	
RTECS Number:	TU4056000
Ingestion:	Oral - Mouse LD50: 1800 mg/kg [Details of toxic effects not reported other than lethal dose value]
Mutagenicity:	Dexamethasone has been found to be negative in the bacterial reverse mutation assay and positive/equivocal in the in vivo chromosomal aberration and micronucleus assays. Dexamethasone has been found to induce apoptosis, which may confound the findings of some genetic toxicology assays. Hence dexamethosone can be considered a non genotoxic apoptosis inducer.
Reproductive Toxicity:	Studies in pregnant animals have shown dexamethasone to be teratogenic and to induce maternal toxicity. Specifically, cleft palate has been identified in mice and rabbits treated with dexamethasone and resorption rates were increased and fetal weights were decreased in exposued animals.
Teratogenicity:	Pregnancy Category C. Use of dexamethasone sodium phosphate in pregnancyrequires that the anticipated benefits be weighed against the potential risks to the mother and fetus.
Other Toxicological Information:	Intraperitoneal - Rat TDLo - Lowest published toxic dose: 1 mg/kg [Vascular - BP elevation not characterized in autonomic section] Intraperitoneal - Rat (Female.19-20days(s) after conception) TDLo - Lowest published toxic dose: 400 ug/kg [Reproductive - Effects on Newborn - growth statistics (e.g.,%, reduced weight gain)] Intraperitoneal - Mouse LD50 - Lethal dose, 50 percent kill: 550 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal - Mouse TDLo - Lowest published toxic dose: 0.2 mg/kg [Gastrointestinal - Other changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - Other enzymes Biochemical - Metabolism (intermediary) - Histamines (including liberation not immunochemical in origin)] Intravenous - Mouse LD50 - Lethal dose, 50 percent kill: 932 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat TDLo - Lowest published toxic dose: 100 mg/kg/10D (Intermittent) [Endocrine - Diabetes mellitus Nutritional and Gross Metabolic - Weight loss or decreased weight gain Biochemical - Metabolism (intermediary) - Lipids including transport] Subcutaneous - Rat TDLo - Lowest published toxic dose: 100 mg/kg/10D (Intermittent) [Endocrine - Diabetes mellitus Blood - Changes in serum composition (e.g., TP, bilirubin, cholesterol) Biochemical - Metabolism (intermediary) - Lipids including transport] Subcutaneous - Rat TDLo - Lowest published toxic dose: 5 mg/kg/2W (Intermittent) [Cardiac - Other changes Vascular - BP elevation not characterized in autonomic section Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - Proteases] Subcutaneous - Mouse (Female.11-14days(s) after conception) TDLo - Lowest published toxic dose: 12800 ug/kg [Reproductive - Fertility - post-implantation mortality (e.g., dead and/or resorbed implants per total number of implants) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Craniofacial (including nose and tongue)] (RTECS)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.

Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Dexamethasone Phosphate :

TSCA Inventory Status:	Listed
EINECS Number:	219-243-0
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	1
HMIS Fire Hazard:	1
HMIS Reactivity:	1
HMIS Personal Protection:	X

SDS Creation Date:	March 18, 2016
SDS Revision Date:	March 18, 2016

SAFETY DATA SHEET

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

Product Identifier

Material Name: Dextrose Injection, USP (Hospira, Inc.)

Trade Name:	Not established
Synonyms:	50% Dextrose Injection, USP Concentrated Dextrose for Intravenous Administration; CONCENTRATED DEXTROSE FOR INTRAVENOUS ADMINISTRATION TO INFANTS
Chemical Family:	Mixture

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

Intended Use: Pharmaceutical product used for electrolyte replacement

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

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)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*
Dextrose, monohydrate	5996-10-1	Not Listed	Not Listed	25-50

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: If irritation occurs or persists, get medical attention. Flush eyes with water as a precaution

Skin Contact: If irritation occurs, wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance.

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: Not an expected route of exposure.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: 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. May include oxides of carbon sodium

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
No special handling requirements for normal use of this material.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:	Store as directed by product packaging.
Incompatible Materials:	None
Specific end use(s):	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
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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia PEAK	5 ppm 7.5 mg/m^3
Austria OEL - MAKs	5 ppm 8 mg/m^3
Belgium OEL - TWA	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	5 ppm 8.0 mg/m^3
Cyprus OEL - TWA	5 ppm 8 mg/m^3
Czech Republic OEL - TWA	8 mg/m^3
Estonia OEL - TWA	5 ppm 8 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m^3
Germany (DFG) - MAK	2 ppm 3.0 mg/m^3
Greece OEL - TWA	5 ppm 7 mg/m^3
Hungary OEL - TWA	8 mg/m^3
Ireland OEL - TWAs	5 ppm 8 mg/m^3
Italy OEL - TWA	5 ppm 8 mg/m^3
Japan - OELs - Ceilings	2 ppm 3.0 mg/m^3
Latvia OEL - TWA	5 ppm 8 mg/m^3
Lithuania OEL - TWA	5 ppm 8 mg/m^3
Luxembourg OEL - TWA	5 ppm 8 mg/m^3
Malta OEL - TWA	5 ppm 8 mg/m^3
Netherlands OEL - TWA	8 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 ppm 8 mg/m^3
Romania OEL - TWA	5 ppm 8 mg/m^3
Slovakia OEL - TWA	5 ppm 8.0 mg/m^3
Slovenia OEL - TWA	5 ppm 8 mg/m^3
Spain OEL - TWA	5 ppm 7.6 mg/m^3
Switzerland OEL -TWAs	2 ppm 3.0 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3

Exposure Controls

Engineering Controls:	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).

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hands:	Not required for the normal use of this product.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product.
Respiratory protection:	None required under normal conditions of use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	**Color:**	Colorless
Odor:	None	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility:	No data available
Water solubility:	7.8 g/100 g @18C
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 HYDROXIDE
No data available
HYDROCHLORIC ACID
No data available
Dextrose, monohydrate
No data available

Decomposition Temperature (°C):	No data available.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	None
Incompatible Materials:	None
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.

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

HYDROCHLORIC ACID
Rat Oral LD 50 238-277 mg/kg
Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

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

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

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. No acute toxicity to aquatic organisms is expected

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

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

15. REGULATORY INFORMATION

Dextrose, monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Data Sources:	Publicly available toxicity information.
Reasons for Revision:	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Revision date:	01-Dec-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

Seeing is believing™

DIPHENHYDRAMINE HYDROCHLORIDE INJECTION 50MG/ML

SAFETY DATA SHEET

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

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

Product Identifier

Product name: Diphenhydramine Hydrochloride Injection 50mg/mL

Intended Use of the Product

Use of the substance/mixture: Pharmaceutical. Antihistamine drug. Use only as directed. Refer to product insert for usage instructions and product information.

Name, Address, and Telephone of the Responsible Party

Supplier:
Mylan Institutional LLC
1718 Northrock Court
Rockford, IL 61103 USA
1-888-258-4199
www.mylan.com

Manufacturer:
Mylan Teoranta
Galway, Ireland

Emergency Telephone Number

Emergency number : +1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

Classification of the Substance or Mixture

Classification (GHS-US)
Not classified

Label Elements

GHS-US labeling No labeling applicable

Other Hazards Not available

Unknown acute toxicity (GHS-US) Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
Diphenhydramine hydrochloride	(CAS No) 147-24-0	1 - 5	Acute Tox. 4 (Oral), H302

Additional Information: sodium hydroxide or hydrochloric acid have been added to adjust the pH to 5-6.
Full text of H-phrases: see section 16

4. FIRST AID MEASURES

Description of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

Most Important Symptoms and Effects Both Acute and Delayed

General: The most frequent adverse reactions include sedation, sleepiness, dizziness, disturbed coordination, epigastric distress, thickening of bronchial secretions.
Inhalation: Inhalation is not considered a potential route of exposure.
Skin Contact: May cause mild skin irritation.
Eye Contact: May cause eye irritation.
Ingestion: May cause nausea, vomiting, diarrhea, gastrointestinal irritation.
Injection: Reactions may vary from central nervous system depression to stimulation. Dry mouth, dilated pupils, flushing of the skin, and gastrointestinal symptoms may also occur.

Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. In the event of accidental injection, go immediately to the nearest emergency room.

5. FIREFIGHTING MEASURES

Extinguishing Media

Suitable extinguishing media: Not flammable. Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media: None known.

Special Hazards Arising From the Substance or Mixture

Fire hazard: Not flammable.
Explosion hazard: Product is not explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.

Advice for Firefighters

Precautionary measures fire: Exercise caution when fighting any chemical fire.
Firefighting instructions: Use water spray or fog for cooling exposed containers.
Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.
Hazardous Combustion Products: Carbon oxides (CO, CO_2). Nitrogen oxides.
Other information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

General measures: Avoid all eye and skin contact and do not breathe vapor and mist.

For Non-Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).
Emergency procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective equipment: Equip cleanup crew with proper protection.

Environmental Precautions Prevent entry to sewers and public waters.

Methods and Material for Containment and Cleaning Up

Methods for cleaning up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

Reference to Other Sections See heading 8, Exposure Controls and Personal Protection.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.
Hygiene measures: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Conditions for Safe Storage, Including Any Incompatibilities

Storage temperature: 15 - 30 °C (59-86°F)
Special rules on packaging: Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate), do not use.

Specific End Use(s) Pharmaceutical. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

No Occupational Exposure Limits (OELs) have been established for this product or its chemical components.

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
Personal protective equipment: Gloves. In case of splash hazard: safety glasses. Protective clothing.
Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.
Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.
Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.
Respiratory protection: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical state	:	Liquid
Appearance	:	Clear
Odor	:	Odorless
Odor threshold	:	Not available
pH	:	5.0-6.0
Relative evaporation rate (butyl acetate=1)	:	Not available
Melting point	:	Not available
Freezing point	:	Not available
Boiling point	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition Temperature	:	Not available
Flammability (solid, gas)	:	Not available
Lower flammable limit	:	Not available
Upper flammable limit	:	Not available
Vapor pressure	:	Not available
Relative vapor density at 20 °C	:	Not available
Relative density	:	Not available
Specific gravity	:	Not available
Solubility	:	Freely soluble in water and alcohol
Log Pow/Kow	:	Not available
Viscosity (kinematic, dynamic)	:	Not available
Explosion data - sensitivity to mechanical impact	:	Not available
Explosion data - sensitivity to static discharge	:	Not available

10. STABILITY AND REACTIVITY

Reactivity Hazardous reactions will not occur under normal conditions.
Chemical Stability Stable under normal conditions.
Possibility of Hazardous Reactions Hazardous polymerization will not occur.
Conditions to Avoid Direct sunlight. Extremely high or low temperatures.
Incompatible Materials Heat sources. Direct sunlight.
Hazardous Decomposition Products Carbon oxides (CO, CO_2). Nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute toxicity: Not classified
LD50 and LC50 Data: Not available
Skin Corrosion/Irritation: Not classified
Serious Eye Damage/Irritation: Not classified
Respiratory or Skin Sensitization: Not classified
Germ Cell Mutagenicity: Not classified
Teratogenicity: Not available
Carcinogenicity: Not classified
Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified
Specific Target Organ Toxicity (Single Exposure): Not classified
Aspiration Hazard: Not classified
Information on Toxicological Effects - Ingredient(s)
LD50 and LC50 Data: Not available

12. ECOLOGICAL INFORMATION

Toxicity Not available
Persistence and Degradability Not available
Bioaccumulative Potential Not available

13. DISPOSAL CONSIDERATIONS

Waste disposal recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.
Additional information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

14. TRANSPORT INFORMATION

In Accordance With ICAO/IATA/DOT/TDG
UN Number Not regulated for transport
UN Proper Shipping Name Not regulated for transport

15. REGULATORY INFORMATION

US Federal Regulations Not applicable
US State Regulations

Diphenhydramine hydrochloride (147-24-0)
U.S. - Texas - Effects Screening Levels - Long Term
U.S. - Texas - Effects Screening Levels - Short Term

Canadian Regulations

Diphenhydramine Hydrochloride Injection 50mg/mL	
WHMIS Classification	Class D Division 1 Subdivision B - Toxic material causing immediate and serious toxic effects

Diphenhydramine hydrochloride (147-24-0)	
Listed on the Canadian DSL (Domestic Substances List) inventory.	
WHMIS Classification	Class D Division 1 Subdivision B - Toxic material causing immediate and serious toxic effects

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

16. OTHER INFORMATION

Revision date : 02/11/2014
Data sources : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.
Other information : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

GHS Full Text Phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
H302	Harmful if swallowed

Party Responsible For The Preparation Of This Document:
Mylan Global Environmental, Health, and Safety Department
Phone Number: 304-599-2595

This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.
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 completeness of the information 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.

North America Mylan Pharmaceuticals

AKORN

SDS: Docu Liquid (Docusate Sodium)

SAFETY DATA SHEET

1. Identification

Product Identifier: Docu Liquid (Docusate Sodium)

Synonyms: Dioctyl sodium sulfosuccinate (DSS)

National Drug Code (NDC): 50383-771-11
50383-771-16

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
Docusate Sodium	577-11-7	Dioctyl sodium sulfosuccinate (DSS)	$C_{20}H_{37}NaO_7S$	444.6	1%

*The formula also contains D&C Red No. 33, Methylparaben, Natural and Artificial Vanilla Flavor, Poloxamer 181, Polyethylene Glycol, Propylene Glycol, Propylparaben, Purified Water and Sodium Benzoate. Sodium Citrate may be used to adjust pH.

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 intended for human consumption under guidance of a physician. Solution is not considered hazardous under normal conditions.
Medical Conditions Aggravated by Exposure:	Do not use if you presently taking mineral oil.
Other Health Warnings:	STOP USE AND ASK A DOCTOR IF: You have rectal bleeding or fail to have a bowel movement after use of this product. This may indicate a serious condition.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or foam as necessary.

Unsuitable Extinguishing Media: With small quantities use carbon dioxide extinguisher. For large fires use ample quantities of water with dry chemicals or foam as necessary.

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 59°F – 86°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
Docusate Sodium	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.
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:	Light pink liquid.
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:	140°F.
Flash Point:	>140°F.
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:	>1.
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.

10. Stability and Reactivity

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

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	No data available.
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:	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.
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.

State Regulations

California Proposition 65:	Not listed.

16. Other Information

NFPA Rating:

Health:	0
Flammability:	2
Reactivity:	0

AKORN

SDS: Docu Liquid (Docusate Sodium)

Revision Date: 05/29/2015

Revision Number: 1

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.

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) :

GHS07 GHS08

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

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

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.

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.

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

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

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

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.

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 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

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

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.

SAFETY DATA SHEET

1. Identification

Product identifier **ENGERIX-B**

Other means of identification

Synonyms ENGERIX B ADULT INJECTION 20 MCG/ML * ENGERIX B 20mcg ADULT * ENGERIX B (ADULT) * ENGERIX-B ADULT VACCINE * ENGERIX B ADULTOS * ENGERIX B ZA ODRASLE * ENGERIX®-B ERWACHSENE * ENGERIX®-B KINDER * ENGERIX B 20 * ENGERIX B INJECTABLE SUSPENSION * ENGERIX B SUSPENSIÓN INYECTABLE * ENGERIX B VACUNA CONTRA LA HEPATITIS B RECOMBINANTE 20MCG/ML * ENGERIX B PAEDIATRIC INJECTION 10 MCG/0.5 ML * ENGERIX B 10 MCG * ENGERIX B PAEDIATRIC * ENGERIX B JUNIOR * HEPATITIS B SURFACE ANTIGEN VACCINE * HEPATITIS B (RECOMBINANT DNA) VACCINE (ADSORBED)

Recommended use Medicinal Product.

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

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

CHEMTREC EMERGENCY NUMBERS

Telephone: +(1) 703 527 3887 (International)
24/7; multi-language response

Contract Number: CCN9484

VERISK 3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

2. Hazard(s) identification

Classified hazards

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

Label elements

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

Hazard(s) not otherwise classified (HNOC)

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

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
ALUMINIUM HYDROXIDE	ALUMIGEL ALUMINA HYDRATED ALUMINA TRIHYDRATE ALPHA-ALUMINA TRIHYDRATE ALUMINIC ACID ALUMINIUM HYDROXIDE ALUMINUM HYDRATE ALUMINUM(III) HYDROXIDE ALUMINUM HYDROXIDE GEL ALUMINUM OXIDE TRIHYDRATE ALUMINUM TRIHYDRATE ALUMINUM TRIHYDROXIDE	21645-51-2	1
DISODIUM HYDROGEN PHOSPHATE	DISODIUM HYDROGEN ORTHOPHOSPHATE PHOSPHORIC ACID, DISODIUM SALT DIBASIC SODIUM PHOSPHATE DISODIUM MONOHYDROGEN PHOSPHATE DSP EXSICCATED SODIUM PHOSPHATE SODA PHOSPHATE DISODIUM PHOSPHORIC ACID SODIUM MONOHYDROGEN PHOSPHATE DISODIUM ACID ORTHOPHOSPHATE DISODIUM HYDROPHOSPHATE HYDROGEN DISODIUM PHOSPHATE DISODIUM HYDROGEN PHOSPHATE ANHYDROUS SODIUM PHOSPHATE DIBASIC DISODIUM PHOSPHATE TRISODIUM PHOSPHATE	7558-79-4	1
HEPATITIS B VIRUS SURFACE ANTIGEN		Unassigned	<1
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT	MERCURATE(1-), ETHYL(2-MERCAPTOBENZOATE(2-)-O, S)-, SODIUM MERCURY, ETHYL(HYDROGEN O-MERCAPTOBENZOATO)-, SODIUM SALT ETHYLMERCURITHIOSALICYLIC ACID, SODIUM SALT SODIUM ETHYLMERCURITHIOSALICYLATE MERCUROTHIOLATE MERTHIOLATE SODIUM THIMEROSAL	54-64-8	0.1
Other components below reportable levels			>96

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

4. First-aid measures

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

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed None known.

Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	No special control measures required for the normal handling of this product. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store at 2 to 8 °C (36 to 46 °F). Do not freeze. Dispose of properly if frozen. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK

Components	Type	Value
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)	8 HR TWA	5000 mcg/m3
	OHC	1

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

Components	Type	Value
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)	Ceiling	0.04 mg/m3
	TWA	0.01 mg/m3

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
ALUMINIUM HYDROXIDE (CAS 21645-51-2)	TWA	1 mg/m3	Respirable fraction.
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)	STEL	0.03 mg/m3	
	TWA	0.01 mg/m3	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

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

Exposure guidelines

US - California OELs: Skin designation

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) Can be absorbed through the skin.

US - Tennessee OELs: Skin designation

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) Can be absorbed through the skin.

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) Can be absorbed through the skin.

Appropriate engineering controls An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

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

Skin protection

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

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

Respiratory protection No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Suspension.Pre-filled syringe.
Vial.

Color Turbid. White

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not 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)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions. DO NOT FREEZE - dispose of properly if frozen.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms related to the physical, chemical and toxicological characteristics	None known.

Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)		
Acute		
Oral		
LD50	Rat	17 g/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Serious eye damage/eye irritation Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization No studies have been conducted.

Skin sensitization None known. 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 Carcinogenic effects are not expected as a result of occupational exposure. Not classifiable as to carcinogenicity to humans.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Contains no ingredient listed as toxic to reproduction

Specific target organ toxicity - single exposure Not assigned.

Specific target organ toxicity - repeated exposure Not assigned.

Aspiration hazard Not established.

Chronic effects Prolonged inhalation may be harmful.

Further information Occupational exposure to the substance or mixture may cause adverse effects.

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.

Components		Species	Test Results
ALUMINIUM HYDROXIDE (CAS 21645-51-2)			
Aquatic			
Acute			
Algae	NOEC	Green algae (Selenastrum capricornutum)	> 100 mg/l, 72 hours
Crustacea	NOEC	Water flea (Daphnia magna)	> 100 mg/l, 48 hours
Fish	NOEC	Brown trout (Adult Salmo trutta)	> 100 mg/l, 96 hours Static renewal test
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	252 mg/l

* Estimates for product may be based on additional component data not shown.

Persistence and degradability Not available.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Mobility in general Not available.

Other adverse effects Not available.

13. Disposal considerations

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

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as a dangerous good.

Not available.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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

15. Regulatory information

US federal regulations

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

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

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

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

US - California Proposition 65 - CRT: Listed date/Developmental toxin

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)	Listed: July 1, 1990

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

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

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

Issue date	05-29-2018
Revision date	05-29-2018
Version #	18
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 1 Flammability: 0 Instability: 0
References	GSK Hazard Determination
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.
Revision information	This document has undergone significant changes and should be reviewed in its entirety.

SAFETY DATA SHEET

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

Product Identifier

Material Name: Epinephrine Injection (Hospira, Inc.)

Trade Name: Not applicable
Chemical Family: Not determined

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

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

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

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

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Epinephrine	51-43-4	200-098-7	Acute Tox. 2 (H300) Acute Tox. 2 (H310)	1.0
Sodium bisulfite	7631-90-5	231-548-0	Acute Tox. 4 (H302)	<2.0
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

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

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

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

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

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

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

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

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:	Store as directed by product packaging.
Specific end use(s):	Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sodium bisulfite

ACGIH Threshold Limit Value (TWA)	5 mg/m^3
Australia TWA	5 mg/m^3
Belgium OEL - TWA	5 mg/m^3
Denmark OEL - TWA	5 mg/m^3
France OEL - TWA	5 mg/m^3
Greece OEL - TWA	5 mg/m^3
Ireland OEL - TWAs	5 mg/m^3
Portugal OEL - TWA	5 mg/m^3
Spain OEL - TWA	5 mg/m^3
Switzerland OEL -TWAs	5 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia PEAK	5 ppm 7.5 mg/m^3
Austria OEL - MAKs	5 ppm 8 mg/m^3
Belgium OEL - TWA	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	5 ppm 8.0 mg/m^3
Cyprus OEL - TWA	5 ppm 8 mg/m^3
Czech Republic OEL - TWA	8 mg/m^3
Estonia OEL - TWA	5 ppm 8 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m^3
Germany (DFG) - MAK	2 ppm 3.0 mg/m^3
Greece OEL - TWA	5 ppm 7 mg/m^3
Hungary OEL - TWA	8 mg/m^3
Ireland OEL - TWAs	5 ppm 8 mg/m^3
Italy OEL - TWA	5 ppm 8 mg/m^3
Japan - OELs - Ceilings	2 ppm 3.0 mg/m^3
Latvia OEL - TWA	5 ppm 8 mg/m^3
Lithuania OEL - TWA	5 ppm 8 mg/m^3
Luxembourg OEL - TWA	5 ppm 8 mg/m^3
Malta OEL - TWA	5 ppm 8 mg/m^3
Netherlands OEL - TWA	8 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 ppm 8 mg/m^3
Romania OEL - TWA	5 ppm 8 mg/m^3
Slovakia OEL - TWA	5 ppm 8.0 mg/m^3
Slovenia OEL - TWA	5 ppm 8 mg/m^3
Spain OEL - TWA	5 ppm 7.6 mg/m^3
Switzerland OEL -TWAs	2 ppm 3.0 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3

Sodium chloride

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Epinephrine

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

Exposure Controls

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

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

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

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

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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Color: Clear colorless
Odor: No data available.
Odor Threshold: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
Solubility: Soluble: Water
pH: 2.2-5.0
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Epinephrine
No data available
Sodium bisulfite
No data available
Water for Injection
No data available
Sodium chloride
No data available
Sodium citrate
No data available
HYDROCHLORIC ACID
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Specific Gravity:	~1
Viscosity:	No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:	The information included in this section describes the potential hazards of the individual ingredients.
Short Term:	May be absorbed through the skin and cause systemic effects. May be absorbed through mucous membranes and cause systemic effects.
Known Clinical Effects:	Adverse effects associated with therapeutic use include increased heart rate (tachycardia), palpitations, sweating, nausea, vomiting, difficulty breathing, dizziness, weakness, headache, anxiety, nervousness.

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

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

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

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

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

Sodium chloride

11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Epinephrine
Embryo / Fetal Development Rat Intravenous Dose not specified Not teratogenic
Embryo / Fetal Development Rabbit Subcutaneous 30 times human dose LOAEL Developmental toxicity
Embryo / Fetal Development Mouse Subcutaneous 7 times human dose LOAEL Developmental toxicity

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

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

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

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

Sodium bisulfite
IARC: Group 3 (Not Classifiable)

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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

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

Epinephrine

RCRA - P Series Wastes	Listed

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

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

Epinephrine

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3 Schedule 4
EU EINECS/ELINCS List	200-098-7

Sodium bisulfite

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-548-0

15. REGULATORY INFORMATION

Water for Injection

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

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

Sodium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Sodium citrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-675-3

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed
Acute toxicity, dermal-Cat.2; H310 - Fatal in contact with skin
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Data Sources: Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision: New data sheet.

Revision date: 03-Nov-2016
Product Stewardship Hazard Communication
Prepared by: Pfizer Global Environment, Health, and Safety Operations

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

End of Safety Data Sheet

Gebauer Company

SAFETY DATA SHEET (SDS)

Section 1: IDENTIFICATION

TRADE NAME	**GEBAUER'S ETHYL CHLORIDE®**	**MANUFACTURER**	Gebauer Company 4444 East 153 Street Cleveland, Ohio 44128
CHEMICAL NAME	Ethyl Chloride	**CONTACT INFORMATION**	Toll Free: (800) 321-9348 Phone: (216) 518-3030 Fax: (216) 581-4970
RECOMMENDED USE	Topical Anesthetic	**IN CASE OF EMERGENCY**	**CHEMTREC - (800) 242-9300 or (703) 527-3887**
FORMULA	C_2H_5Cl	**CHEMICAL FAMILY**	Halogenated Hydrocarbon

Section 2: HAZARDS IDENTIFICATION

Health Rating	2 - Moderate
Flammability Rating	4 - Acute
Reactivity Rating	0 - None
Special Rating	None
Lab Protective Equipment	Neoprene or Viton gloves, lab coat, goggles or face shield, vent hood.
Storage Color Code	Red (Flammable)

Hazard Category	Signal Word	Hazard Statement	Pictogram	Precautionary Statement
Flammable Gas (Category 1)	Danger	Extremely flammable gas		Keep away from heat/sparks/open flames/hot surfaces/cautery equipment – No smoking.
Compressed Gas	Warning	Contains gas under pressure; may explode if heated		Store is a well-ventilated place.
Eye Irritation (Category 2B)	Warning	Causes eye irritation	N/A	If product gets into eyes, see the Section 4: First Aid Measures.
Acute Toxicity (Category 4)	Warning	Harmful if inhaled		If inhaled, see the Section 4: First Aid Measures.

Cause		Effects
Potential Acute Health Effects	Inhalation	Headache, dizziness, nausea, vomiting, loss of coordination and disorientation may produce narcotic and anesthetic effects. May produce central nervous system depression, respiratory paralysis, or fatal coma with respiratory or cardiac arrest. May sensitize the myocardium to endogenous epinephrine, causing dangerous dysrhythmias. Although absorbed through lungs and skin, it also is rapidly given off through the lungs.
	Ingestion	Unlikely route of exposure due to gaseous nature.
	Skin Contact	Rapid evaporation of liquid may cause frostbite. Symptoms of frostbite are blanching of the skin, cold feeling numbness. Cutaneous sensitization may occur, but is extremely rare. Freezing can occasional alter pigmentation. A single prolonged skin exposure is not likely to result in absorption of harmful amounts
	Chronic Exposure	Long term exposure to high levels may produce the following: loss of muscle coordination, involuntary eye movements, tremors, speech disturbance, sluggish reflexes and hallucinations. These symptoms are alleviated when the overexposure is ended.
	Aggravation of Preexisting Conditions	The defatting properties of Ethyl Chloride may aggravate existing dermatitis.

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Concentration	OSHA PEL	ACGIH TLV-TWA
Ethyl Chloride	Chloroethane, Hydrochloric Ether	75-00-3	>99	1000ppm	100ppm

Section 4: FIRST AID MEASURES

Inhalation	Immediately remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, qualified personnel may give oxygen. Call a physician.
Ingestion	Unlikely route of exposure due to gaseous nature.
Skin Contact	For exposure to liquid, immediately warm frostbite area with warm water not to exceed 105ºF (41ºC). In case of massive exposure, remove contaminated clothing while showering with warm water. Call a physician.
Eye Contact	For exposure to liquid, check for and remove any contact lenses. Immediately flush eyes thoroughly with warm water for at least 15 minutes. Hold the eyelids open and away from the eyeballs to ensure that all surfaces are flushed thoroughly. See a physician, preferably an ophthalmologist, immediately.

Section 5: FIRE FIGHTING MEASURES

Special Fire Fighting Procedures

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

Unusual Fire and Explosion Hazards

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

Section 6: ACCIDENTAL RELEASE MEASURES

Spill and Leak Response

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

Waste Disposal Method

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

Section 7: HANDLING AND STORAGE

Storage Precautions

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

Handling Precautions

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

Section 8: EXPOSURE CONTROLS – PERSONAL PROTECTION

Engineering Controls	Use with adequate ventilation.
Respiratory Protection	For clinical setting: minimize inhalation of vapors by patient, especially when applying to head and neck. For large spills (≥ 1000 ppm twa and ≤ 3800 ppm instantaneous exposure): full face, positive pressure , self-contained breathing apparatus should be available for emergency use.
Skin Protection	Wear neoprene or viton gloves for exposures ≥1000 ppm TWA and ≤3800 ppm instantaneous exposure.
Eye Protection	Splash goggles or safety glasses.
Exposure Limits	OSHA – 1000ppm PELACGLIH – 100 ppm TLV, A3 IDHL – 3800 ppm LEL ACGIH – 100ppm TLV

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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

Section 10: STABILITY AND REACTIVITY

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

Section 11: TOXICOLOGICAL INFORMATION

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

Section 11: TOXICOLOGICAL INFORMATION (Continued)

Mutagenesis	Has been shown to be mutagenic in bacteria, with and without activation. A 2-year study in mice did not yield increases in bone marrow micronuclei.
Reproductive/Developmental	No teratogenic effects were observed in mice exposed to 500, 1500 or 5000 ppm during organogenesis . No effects on reproductive organs were observed after 13 weeks exposure to vapors.

Section 12: ECOLOGICAL INFORMATION

Environmental Stability	Gas is dissipated rapidly in a ventilated area.
Effect on Plants and Animals	Suspected to have toxic effects with long term exposure to: central nervous system depression, liver and kidney. No information on adverse effects to plant life except for frost produced upon evaporation.
Effect on Aquatic Life	No evidence currently available.

Section 13: DISPOSAL CONSIDERATIONS

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

Section 14: TRANSPORT INFORMATION

Proper Shipping Name	Ethyl Chloride
Hazard Class	2.1 (Flammable Gas)
Identification Number	UN 1037
Packing Group	I (49 CFR 173.322)
Reportable Quantity	100 LBS./45.4 Kg
DOT Label(s) Required	Flammable Gas
Canada TDG Description	Ethyl Chloride, Class 2.1, UN1037 **Special Commodity**

Section 15: REGULATORY INFORMATION

USA TSCA:	Listed	**Canada DSL:**	Listed	**Korea ECL:**	Listed
Europe EINECS:	Listed	**Australia AICS:**	Listed	**Japan MITI (ENCS):**	Listed

SARA Title III	Section 302: Not listed. Sections 311, 312: Acute health hazard. Section 313: Listed.		
CERCLA	Listed with a reportable quantity of 100 lbs.		
State Regulatory Information: Ethyl Chloride is covered under the specific State regulations listed.	Alaska California Florida Massachusetts Michigan Minnesota Missouri New Jersey New York Pennsylvania Rhode Island Texas West Virginia Wisconsin	Designated Toxic and Hazardous Substances Permissible Exposure Limits for Chemical Contaminants Substance List Substance List Critical Materials Register List of Hazardous Substances Employer Information/Toxic Substance List Right to Know Hazardous Substance List Hazardous Substance List Regulated Substance List Hazardous Substance Hazardous Substance List Hazardous Substance List Toxic and Hazardous Substances	**CANADA Regulations (WHMIS):** Class A – Compressed Gas Class B1 – Flammable Gas Canadian NPRI – Listed **EUROPEAN UNION CLASSIFICATION:** Hazard Symbol: F+; Xn Risk Phrases: R12-40-52/53 Safety Phrases: S(2-) 9-16-33-36/37-61
California Proposition 65:	Ethyl Chloride is on the California Proposition 65 lists. This product contains a chemical known to the State of California to cause cancer.		

Section 16: OTHER INFORMATOIN

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

SAFETY DATA SHEET

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

Product Identifier

Material Name: Furosemide Injection (Hospira, Inc.)

Trade Name: Not established
Chemical Family: Not determined

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

Intended Use: Pharmaceutical active

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2

Label Elements

Signal Word: Warning
Hazard Statements: H361d - Suspected of damaging the unborn child

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

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

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

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

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

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

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

4. FIRST AID MEASURES

Description of First Aid Measures

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

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

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

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

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

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

7. HANDLING AND STORAGE

Precautions for Safe Handling

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

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit: 2 ppm

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia PEAK	5 ppm 7.5 mg/m^3
Austria OEL - MAKs	5 ppm 8 mg/m^3
Belgium OEL - TWA	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	5 ppm 8.0 mg/m^3
Cyprus OEL - TWA	5 ppm 8 mg/m^3
Czech Republic OEL - TWA	8 mg/m^3
Estonia OEL - TWA	5 ppm 8 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m^3
Germany (DFG) - MAK	2 ppm 3.0 mg/m^3
Greece OEL - TWA	5 ppm 7 mg/m^3
Hungary OEL - TWA	8 mg/m^3
Ireland OEL - TWAs	5 ppm 8 mg/m^3
Italy OEL - TWA	5 ppm 8 mg/m^3
Japan - OELs - Ceilings	2 ppm 3.0 mg/m^3
Latvia OEL - TWA	5 ppm 8 mg/m^3
Lithuania OEL - TWA	5 ppm 8 mg/m^3
Luxembourg OEL - TWA	5 ppm 8 mg/m^3
Malta OEL - TWA	5 ppm 8 mg/m^3
Netherlands OEL - TWA	8 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 ppm 8 mg/m^3
Romania OEL - TWA	5 ppm 8 mg/m^3
Slovakia OEL - TWA	5 ppm 8.0 mg/m^3
Slovenia OEL - TWA	5 ppm 8 mg/m^3
Spain OEL - TWA	5 ppm 7.6 mg/m^3
Switzerland OEL -TWAs	2 ppm 3.0 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3

SODIUM HYDROXIDE

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Bulgaria OEL - TWA	2.0 mg/m^3
Czech Republic OEL - TWA	1 mg/m^3
Estonia OEL - TWA	1 mg/m^3
France OEL - TWA	2 mg/m^3
Greece OEL - TWA	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Japan - OELs - Ceilings	2 mg/m^3
Latvia OEL - TWA	0.5 mg/m^3
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	0.5 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	1 mg/m^3
Switzerland OEL -TWAs	2 mg/m^3

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

Furosemide

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

Exposure Controls

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

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

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

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

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	**Color:**	No data available.
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

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

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** No data available
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

Polymerization: No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable at normal conditions
Possibility of Hazardous Reactions
- **Oxidizing Properties:** No data available
- **Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
Short Term: Ingestion may cause lowering of blood pressure. Accidental or incidental ingestion of large amounts may cause nausea, abdominal discomfort, headache or dizziness. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

11. TOXICOLOGICAL INFORMATION

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

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

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

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

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

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

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

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

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

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

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

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

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

Furosemide
IARC: Group 3 (Not Classifiable)

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

11. TOXICOLOGICAL INFORMATION

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

This material is not regulated for transportation / carriage.

15. REGULATORY INFORMATION

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

Furosemide

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

15. REGULATORY INFORMATION

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

Water for Injection

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

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

SODIUM HYDROXIDE

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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

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

Reasons for Revision: New data sheet.

Revision date: 31-Mar-2017

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

Gardasil®

SAFETY DATA SHEET

IMPORTANT NOTICE **This Safety Data Sheet (SDS) is prepared by Seqirus Pty. Ltd. in accordance with Safe Work Australia National Code of Practice for the Preparation of Safety Data Sheets (February 2016). The information contained herein must not be altered or deleted. Additional information may be appended to the SDS, but it must be marked clearly to indicate that it is not part of the original.**

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product Name	Gardasil®
Other Names	Human Papillomavirus Quadrivalent (types 6, 11, 16 and 18), Vaccine, Recombinant: HPV Vaccine
Manufacturer's Product Code	S30383, S30384, S30385, S30386
Use	Vaccine indicated for the prevention of cancer, precancerous or dysplastic lesions, genital warts, and infection caused by the Human Papillomavirus (HPV) types 6, 11, 16 and 18.
Supplier Name	Seqirus Pty Ltd (ABN 26 160 735 035)
Address	63 Poplar Road, Parkville, Victoria 3052, Australia
Telephone	+61 3 9389 2000
Emergency Telephone	+61 3 9389 1984 (24hr)

2. HAZARDS IDENTIFICATION

Not classified as a hazardous chemical according to Australian WHS Regulations

GHS Classification(s)	None Allocated
Signal Word	No Signal Word
Pictogram(s)	No Pictogram(s)
Hazard Statement(s)	None Allocated
Prevention statement(s)	None Allocated
Response	None Allocated
Storage	None Allocated
Disposal	None Allocated

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name:	*CAS Number:*	*Proportion:*
HPV L1 VLPs	-	<0.03%
Other non-hazardous ingredients	-	Up to 100%

4. FIRST AID MEASURES

Eye In case of contact, flush eyes with plenty of water. Get medical attention if symptoms occur.

Swallowed DO NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed call physician immediately.

Skin In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before use.

Inhaled If inhaled remove to fresh air. If breathing is difficult, give oxygen. If not breathing give artificial respiration. Get medical attention if symptoms occur.

First Aid Facilities Ensure water is available at point of use.

Advice to Doctor Treat symptomatically.

5. FIRE FIGHTING MEASURES

Fire/Explosion Hazard None known.

Fire Extinguishing Media
- Dry chemical powder
- Water spray or fog
- Foam
- Carbon Dioxide

Hazchem Code None allocated

6. ACCIDENTAL RELEASE MEASURES

Minor Spills
- Contain spilled material.
- Use absorbent (or soil in the absence of other suitable material)
- Scoop up material and place in a sealed, liquid-proof container for disposal.

Major Spills	- Contain material ensuring runoff does not reach a waterway. - Place spilled material in an appropriate container for disposal. - Minimise contact of spilled material with solid to prevent runoff to surface waterways.

7. HANDLING AND STORAGE

- Avoid contact with skin and eyes.
- Keep it where children cannot reach it.
- Store at 2 to 8 degrees Celsius.
- Do not freeze vaccine.
- Protect the injection from light be it keeping it in the original pack until it is time for it to be given.
- Do not use after the expiry date on the label.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards	No exposure limits set by SWA or ACGIH
Engineering Controls	Adequate ventilation should be provided if there is a risk of aerosol formation.
Personal Protection	None is required when handling sealed vials. Safety glasses and protective gloves should be worn when handling bulk liquid formulation or filling vials. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Cloudy, white liquid
Odour	Not determined
pH	Not determined
Boiling Point/Melting Point	Not determined
Vapour Pressure	Not determined
Vapour Density	Not determined
Specific Gravity	Not determined
Flashpoint	Not determined
Flammability Limits	Not determined
Solubility in Water	Not determined

10. STABILITY AND REACTIVTY

Reactivity Not available

Stability Not available

Decomposition Products None known

11. TOXICOLOGICAL INFORMATION

Toxicity Data HPV L1 VLPs- in mouse- no adverse effects except local irritation

Effects of Acute Exposure

Eye Formulation may be irritating

Swallowed Not available

Skin Formulation may be irritating

Inhaled Not available

Chronic Health Effects Gardasil® is a vaccine indicated for the prevention of cancer, precancerous or dysplastic lesions, genital warts, and infection caused by the Human Papillomavirus (HPV) types targeted by the vaccine. Gardasil® contains L1 VLPs, which are proteins that resemble wild-type virions. Because the virus-like particles contain no viral DNA, they cannot infect cells or reproduce. The most commonly reported side effects include pain, swelling, itching and redness at the injection site, fever, nausea, dizziness and vomiting. Gardasil® in contraindicated in individuals hypersensitive to any components of the vaccine. Gardasil® is not recommended for pregnant women.

It is not given chronically, but when injected 3 times in laboratory animals in 13-week repeated dose intramuscular toxicity study, the primary effects were local irritation at the injection site and enlargement of the draining lymph nodes. There was also an antibody response as expected. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/fetal development, parturition or postnatal development. Gardasil® induced a specific antibody response against HPV Types 6, 11, 16 and 18 in pregnant rats following one or multiple intramuscular injections. Antibodies against all 4 HPV types were transferred to the offspring during gestation and possibly during lactation.

12. ECOLOGICAL INFORMATION

- No data available.

13. DISPOSAL CONSIDERATIONS

- Avoid contact of spilled material and runoff with soil and surface waterways.
- Dispose of or treat any spills residues including contaminated soils following all applicable local regulations.

14. TRANSPORT INFORMATION

Not Classified as a dangerous good by the criteria of the ADG Code

UN Number	None allocated
DG Class	None allocated
Subsidiary Risk	None allocated
Packing Group	None allocated
Hazchem Code	None allocated

15. REGULATORY INFORMATION

Poisons Schedule Number	Schedule 4 (S4) – Prescription only medicine

16. OTHER INFORMATION

Last Revised	15 November 2016
Reason for Revision	- Update to GHS requirements - Update Business contact details - Update Composition and Physical properties information - Updated NOHSC to SWA

Abbreviations

SWA	- Safe Work Australia
GHS	- Globally Harmonised System
WHS	- Work, Health and Safety
ADG Code	- Australian Dangerous Goods Code
UN Number	- United Nations Number
DG Class	- Dangerous Goods Class
CAS Number	- Chemical Abstract Service Number

Contact Point

Company Contact:	+61 3 9389 1984 (24hr)
Australian Poisons Information Centre, 24 hour service:	13 11 26
Australian Police, Fire Brigade or Ambulance:	000
New Zealand Poisons Information Centre, 24 hour service:	0800 764 766
New Zealand Police, Fire Brigade or Ambulance:	111

Whilst the information contained in this document is based on data which, to the best of our knowledge, was accurate and reliable at the time of preparation, no responsibility can be accepted by us for errors and omissions. Users are advised to make their own determination as to the suitability of this information in relation to their particular purposes and specific circumstances. Since the information contained in this document may be applied under conditions beyond our control, we can accept no responsibility for any loss or damage by any person acting or refraining from action as a result of this information.

SAFETY DATA SHEET

Product Name: Gentamicin Sulfate in 0.9% Sodium Chloride 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	Gentamicin Sulfate in 0.9% Sodium Chloride Injection
Synonyms	Gentamicin Sulfate, USP; 0-3-Deoxy-4-C-methyl-3(methylamino)-ß-L-arabinopyranosyl-(1-> 6 -0-[2,6-diamino-2,3,4,6-tetradeoxy-α-D-erythro-hexopyranosyl-(l->4)]-2-deoxy-D-streptamine.

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Gentamicin Sulfate in 0.9% Sodium Chloride Injection is a solution containing gentamicin sulfate, a complex aminoglycoside antibiotic substance with three components, sulfates of gentamicin C1, gentamicin C2 and gentamicin C1A. Clinically, gentamicin sulfate is used to treat severe systemic infections due to sensitive Gram-negative and other organisms. In the workplace, this material should be considered potentially irritating to the eyes and respiratory system, a potential sensitizer, and a potential occupational reproductive hazard. Based on clinical use, possible target organs include the kidneys, hearing, nervous system, and gastrointestinal system.

U.S. OSHA GHS Classification

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

Health Hazards	**Hazard Class**	**Hazard Category**
	Sensitization – Respiratory	1
	Sensitization – Skin	1
	Toxic to Reproduction	2

Label Element(s)

Pictogram

Signal Word Danger

Hazard Statement(s)

May cause allergy or asthma symptoms or breathing difficulties if inhaled
May cause an allergic skin reaction
Suspected of damaging fertility or the unborn child

2. HAZARD(S) IDENTIFICATION: continued

Precautionary Statement(s)

Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Avoid breathing vapors/spray
In case of inadequate ventilation, wear respiratory protection
Contaminated work clothing must not be allowed out of the workplace
Wash hands thoroughly after handling

Response

If exposed or concerned: Get medical advice/attention.

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.

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.

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Gentamicin Sulfate
Chemical Formula NA

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Gentamicin Sulfate	<0.5	1405-41-0	LY2625000

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride. Sulfuric acid and/or sodium hydroxide are added for pH adjustment.

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.

Product Name: Gentamicin Sulfate in 0.9% Sodium Chloride Injection

Hospira

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.

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. Employees with known allergies to gentamicin sulfate or related antibiotics should consult a health and/or safety professional prior to handling open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Gentamicin Sulfate	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. Since protection provided by air purifying respirators is limited, a powered air purifying respirator or supplied air should be considered during an uncontrolled release event, if exposure levels are not known, or during events where air-purifying respirators may not provide adequate protection. 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.

Product Name: Gentamicin Sulfate in 0.9% Sodium Chloride Injection

Hospira

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	A sterile, nonpyrogenic solution
Odor	NA
Odor Threshold	NA
pH	3.8 (3.0 to 5.5)
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	Gentamicin Sulfate is soluble in water, moderately soluble in methanol, ethanol, acetone and practically insoluble in benzene.
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	Not determined
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 sulfur oxides (SOx).
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
Gentamicin Sulfate	100	LD50	Oral	> 5000 > 11,269 > 9050	mg/kg mg/kg mg/kg	Rat Mouse Mouse
Gentamicin Sulfate	100	LD50	Intravenous	96 47 75	mg/kg mg/kg mg/kg	Rat Mouse Mouse
Gentamicin Sulfate	100	LD50	Intraperitoneal	630 245 430	mg/kg mg/kg mg/kg	Rat Mouse Mouse

LD 50: Dosage that produces 50% mortality.

Product Name: Gentamicin Sulfate in 0.9% Sodium Chloride Injection

Hospira

11. TOXICOLOGICAL INFORMATION: continued

Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. In clinical use, adverse effects may include nausea, vomiting, diarrhea, headache, depression, dizziness, impaired balance and eye irritation, skin rashes, respiratory depression, possible kidney injury and hearing loss. Nephrotoxicity manifested by an elevated BUN or serum creatinine level or a decrease in the creatinine clearance has been reported with gentamicin. Gentamicin has produced vestibular and auditory toxicity in man and in experimental animals. Neurotoxicity manifested by ototoxicity, both vestibular and auditory, can occur in patients treated with gentamicin sulfate. Gentamicin-induced ototoxicity is usually irreversible. Allergic reactions have also been reported.
Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/ Corrosion	None anticipated from normal handling of this product.
Ocular Irritation/ Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation. Gentamicin sulfate produced significant conjuctival irritation in an irritation study in animals.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. Allergic reactions have been reported during the clinical use of this product in patients.
Reproductive Effects	None anticipated from normal handling of this product. Animal reproduction studies conducted on rats and rabbits did not reveal evidence of impaired fertility or harm to the fetus due to gentamicin sulfate. Aminoglycoside antibiotics cross the placenta, and there have been several reports of total irreversible bilateral congenital deafness in children whose mothers received streptomycin or tobramycin during pregnancy. Also, aminoglycosides may be nephrotoxic in the human fetus. FDA Pregnancy Category D.
Mutagenicity	The mutagenic potential of gentamicin sulfate has not been evaluated.
Carcinogenicity	The carcinogenic potential of gentamicin sulfate has not been evaluated.
Carcinogen Lists	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	Gentamicin has produced vestibular and auditory toxicity in patients and experimental animals. Based on clinical use, possible target organs include the kidneys, hearing, nervous system, and gastrointestinal 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.

Notes:

Product Name: Gentamicin Sulfate in 0.9% Sodium Chloride Injection

Hospira

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORTATION INFORMATION

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

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	This product contains an aminoglycoside, a chemical known to the State of California to cause developmental reproductive toxicity.

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

Product Name: Gentamicin Sulfate in 0.9% Sodium Chloride Injection

Hospira

15. REGULATORY INFORMATION: continued

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

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Avoid breathing vapors/spray
In case of inadequate ventilation, wear respiratory protection
Contaminated work clothing must not be allowed out of the workplace
Wash hands thoroughly after handling

Response

If exposed or concerned: Get medical advice/attention.

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.

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.

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

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
R42/43 - May cause sensitization by inhalation and skin contact

Product Name: Gentamicin Sulfate in 0.9% Sodium Chloride Injection

Hospira

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 18, 2012
Date Revised:	June 02, 2014

Disclaimer:
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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] hydrogenchloride (active ingredient)	(CAS No) 16941-32-4	100	Skin Sens. 1, H317

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.

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

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.

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] hydrogenchloride (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

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 Medicaine: 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.

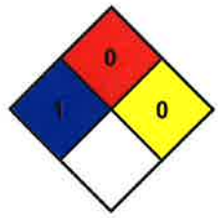
Full text of H-phrases: see section 16:

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. Identification

Product identifier **HEPATYRIX**

Other means of identification

Synonyms COMBINED INACTIVATED HEPATITIS A AND PURIFIED VI POLYSACCHARIDE TYPHOID VACCINE

Recommended use Medicinal Product

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

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

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

2. Hazard(s) identification

Classified hazards

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

Label elements

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

Hazard(s) not otherwise classified (HNOC)

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

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
HEPATITIS A VIRUS INACTIVATED	HEPATITIS A VIRUS INACTIVATED	Unassigned	<1
VI POLYSACCHARIDE OF SALMONELLA TYPHI		Unassigned	<1
Other components below reportable levels			>99

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

4. First-aid measures

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

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed	None known.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	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. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Do not freeze.

8. Exposure controls/personal protection

Occupational exposure limits

GSK
Not established

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	No particular ventilation requirements.

Individual protection measures, such as personal protective equipment

Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
Skin protection	
Other	Wear appropriate chemical resistant clothing.
Respiratory protection	No personal respiratory protective equipment normally required.

Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Pre-filled syringe. or Vial.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.

Solubility(ies)

Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Do not freeze.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Symptoms related to the physical, chemical and toxicological characteristics	None known.

Information on toxicological effects

Acute toxicity	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
Skin corrosion/irritation	Health injuries are not known or expected under normal use.
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use. Due to partial or complete lack of data the classification is not possible.

Respiratory or skin sensitization

Respiratory sensitization	Not available.
Skin sensitization	None known.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	Due to partial or complete lack of data the classification is not possible.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity	Due to partial or complete lack of data the classification is not possible.
Specific target organ toxicity - single exposure	None known.
Specific target organ toxicity - repeated exposure	None known.
Aspiration hazard	Not likely, due to the form of the product.
Further information	Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity	No information is available about the potential of this product to produce adverse environmental effects.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	Not available.

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 a dangerous good.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations One or more components are not listed on TSCA.

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

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

Not regulated.

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

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

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

Not listed.

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

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

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

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

Issue date 06-24-2014

Revision date 06-24-2014

Version # 10

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

HMIS® ratings
Health: 1
Flammability: 0
Physical hazard: 0

NFPA ratings
Health: 1
Flammability: 0
Instability: 0

References GSK Hazard Determination

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

Revision Information
Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Undisclosed Ingredient Statement
Physical & Chemical Properties:
Regulatory Information: United States

SAFETY DATA SHEET

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

Product Identifier

Material Name: Ibuprofen 40 mg/mL (Oral Suspension)

Trade Name: IBUPIRAC; IBUPROFENE; IBUPROFENO
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product used as Non-steroidal, anti-inflammatory drug (NSAID) antipyretic

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
1 Giralda Farms
Madison, NJ 07940

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

EU Classification:

EU Indication of danger: Not classified

Label Elements

Other Hazards No data available
Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%

3. COMPOSITION / INFORMATION ON INGREDIENTS					
Ibuprofen	15687-27-1	239-784-6	Repr.Cat3;R62-63 Xn;R22	Acute Tox.4 (H302) Repr.2 (H361fd)	4
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Amaranth	915-67-3	213-022-2	Not Listed	Not Listed	*
Carboxymethylcellulose sodium	9004-32-4	Not Listed	Not Listed	Not Listed	*
Flavor	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	Not Listed	*
Monoammonium glycyrrhizinate	53956-04-0	258-887-7	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	Not Listed	*
Simethicone emulsion	67762-90-7	Not Listed	Not Listed	Not Listed	*
Sodium cyclamate	139-05-9	205-348-9	Not Listed	Not Listed	*
Sodium Lauryl Sulfate	151-21-3	205-788-1	Not Listed	Not Listed	*
Sodium saccharin	128-44-9	204-886-1	Not Listed	Not Listed	*
Sorbitol solution	50-70-4	200-061-5	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	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 R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

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

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

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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

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

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing dust, 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.

Ibuprofen

Pfizer OEL TWA-8 Hr:	3000µg/m^3

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Estonia OEL - TWA	10 mg/m^3
France OEL - TWA	10 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ireland OEL - TWAs	10 mg/m^3 4 mg/m^3
Latvia OEL - TWA	2 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Romania OEL - TWA	10 mg/m^3
Russia OEL - TWA	6 mg/m^3
Spain OEL - TWA	10 mg/m^3
Switzerland OEL -TWAs	3 mg/m^3
Vietnam OEL - TWAs	10 mg/m^3 5 mg/m^3

Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Bulgaria OEL - TWA	10.0 mg/m^3
Estonia OEL - TWA	10 mg/m^3
France OEL - TWA	10 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
Latvia OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	10 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Slovakia OEL - TWA	6 mg/m^3
Spain OEL - TWA	10 mg/m^3

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Suspension	**Color:**	Pink
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient: (Method, pH, Endpoint, Value)
Polysorbate 80
No data available
Ibuprofen
No data available
Carboxymethylcellulose sodium
No data available
Microcrystalline cellulose
No data available
Sorbitol solution
No data available
Sucrose
No data available
Sodium cyclamate
No data available
Sodium saccharin
No data available
Monoammonium glycyrrhizinate
No data available
Sodium Lauryl Sulfate
No data available
Simethicone emulsion
No data available
Methylparaben
No data available
Propylparaben
No data available
Flavor
No data available
Water, purified
No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

10. STABILITY AND REACTIVITY

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: Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Acute overdosage and/or chronic abuse of ibuprofen may cause kidney effects.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus

Known Clinical Effects: Adverse effects associated with therapeutic use include gastrointestinal effects such as nausea, pain, heartburn, bleeding, ulceration, and perforation Drowsiness, fatigue, or headache are also possible. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

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

Polysorbate 80
Rat Oral LD50 25 g/kg

Ibuprofen
Rat Oral LD 50 1600 mg/kg
Rat Inhalation LC 50 > 20mg/L

Carboxymethylcellulose sodium
Mouse Oral LD50 > 27,000 mg/kg
Rat Oral LD50 27,000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Sorbitol solution
Rat Oral LD50 15,900 mg/kg
Mouse Oral LD50 17,800mg/kg

Sucrose
Rat Oral LD50 29.7 g/kg

Sodium cyclamate
Rat Oral LD50 1280 mg/kg

Sodium saccharin
Mouse Oral LD50 17.5 g/kg
Rat Oral LD50 14.2 - 17g/kg

11. TOXICOLOGICAL INFORMATION

Rat Intraperitoneal LD50 7100mg/kg

Sodium Lauryl Sulfate
Rat Oral LD 50 1288 mg/kg
Rat Sub-tenon injection (eye) LD 50 210mg/kg

Propylparaben
Mouse Oral LD 50 6332 mg/kg
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg
Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

Ibuprofen
4 Day(s) Rat Oral 200 mg/kg Gastrointestinal System
30 Day(s) Dog Oral 480 mg/kg Gastrointestinal system
2 Week(s) Rat Oral 1300 mg/kg Liver

Carboxymethylcellulose sodium
13 Week(s) Rat Oral 227 g/kg LOAEL Liver, Kidney, Ureter, Bladder

Sodium saccharin
36 Week(s) Rat Oral 756 g/kg LOAEL Kidney, Ureter, Bladder
54 Day(s) Rat Oral 32400 mg/kg LOAEL Immune system

Sodium Lauryl Sulfate
3 Day(s) Rat Oral 75 mg/kg LOAEL Liver, Blood

Propylparaben
3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

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

Ibuprofen
Fertility and Embryonic Development Rat rectal 100 mg/kg/day Fertility
Fertility and Embryonic Development Rat rectal 200 mg/kg/day Fetotoxicity
Embryo / Fetal Development Rabbit Oral 60 mg/kg/day Not Teratogenic
Embryo / Fetal Development Rat Oral 180 mg/kg/day Not Teratogenic

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

Ibuprofen
Bacterial Mutagenicity (Ames) *Salmonella* Negative

11. TOXICOLOGICAL INFORMATION

Sucrose
Bacterial Mutagenicity (Ames) *Salmonella* Negative

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

Sodium cyclamate
IARC: Group 3 (Not Classifiable)

Sodium saccharin
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided. See aquatic toxicity data for individual components below:

Toxicity:

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

Ibuprofen
Daphnia magna (Water Flea) EC50 48 Hours 108 mg/L
Desmodesmus subcapitata (Green Alga) EC50 72 Hours 315 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications
WHMIS hazard class:
None required

Amaranth

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	213-022-2

Carboxymethylcellulose sodium

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

Flavor

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Ibuprofen

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 Schedule 4
EU EINECS/ELINCS List	239-784-6

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

Microcrystalline cellulose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present

15. REGULATORY INFORMATION

Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9

Monoammonium glycyrrhizinate

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	258-887-7

Polysorbate 80

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

Propylparaben

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	202-307-7

Simethicone emulsion

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

Sodium cyclamate

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	205-348-9

Sodium Lauryl Sulfate

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 6
EU EINECS/ELINCS List	205-788-1

Sodium saccharin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-886-1

Sorbitol solution

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-061-5

Sucrose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

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

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Reproductive toxicity-Cat.2; H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

Toxic to Reproduction: Category 3
Xn - Harmful

R22 - Harmful if swallowed.
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.

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

Revision date: 05-Nov-2014
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

nephron pharmaceuticals corporation

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.

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, difficultybreat hing 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 Solution3.0mg 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.

SECTION 16: OTHER INFORMATION

REVISION DATE: 02-09-2015

REVISION DATE: 07-22-2004 SUPERSEDES: 01-23-2003
REVISION DATE: 06-26-2014 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.

Safety Data Sheet

Bristol-Myers Squibb Company

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

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

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

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

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

4. FIRST AID MEASURES	
Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. If exposed or concerned: Get medical attention/advice.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Discard contaminated clothing or wash before re-use. If exposed or concerned: Get medical attention/advice.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. If exposed or concerned: Get medical attention/advice.
Ingestion	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. If exposed or concerned: Get medical attention/advice.
Notes to Physician	Medical conditions aggravated include: diabetes, liver disorders, infection, immunodeficiency, hypertension, myasthenia gravis, osteoporosis, peptic ulcer, psychotic disorders, colitis, kidney disorders. This product has been reported to interact with the following medications: diuretic, cyclosporine, immunosuppressants, NSAID (non-steroidal antiinflammatory drugs), drugs metabolized by cytochrome P-450, drugs that cause hyperglycemia, oral hypoglycemic drugs, neuromuscular blocking agents, fluoroquinoline antibiotics, certain vaccines, drugs that inhibit cytochrome P-450. Refer to Section 11.
Medical Surveillance	The need for a pre-placement physical examination and history for employees with potential exposure to this compound is to be evaluated by a physician that is thoroughly knowledgeable about both the toxicity of this compound and the extent of work place exposure. Baseline testing would include: blood glucose test, a complete blood count with differential, a blood test for liver function, a blood test for kidney function. Based on opportunity for exposure and duration of exposure a periodic follow-up examination may be considered. Employees who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.

5. FIRE-FIGHTING MEASURES	
Flammable Properties	Not available
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
Protection of Firefighters	Specific hazards: Refer to HAZARDS IDENTIFICATION section for a description of hazards for this material. Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: carbon oxides (COx), hydrogen halides Further Information: HCl gas can form flammable or explosive mixtures with alcohols or metals. In the event of fire and/or explosion do not breathe fumes.
Other information	Decontaminate protective clothing and equipment before reuse.

6. ACCIDENTAL RELEASE MEASURES	
Personal precautions	Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, lab coat and impervious gloves. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.
Environmental precautions	Prevent release to drains and waterways. Prevent release to the environment.
Containment Methods	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).
Cleanup Methods	Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Clean area with detergent and water after spill pick-up, if appropriate. Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials.

7. HANDLING AND STORAGE	
Handling Precautions	Avoid exposure - obtain special instructions before use. Avoid inhalation of vapour or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Container Requirements	Store in sturdy containers appropriate to maintain the integrity of this material for its intended use. Store in spill containment pallet or other device to confine spills.
Storage Conditions	Store at room temperature. Protect against light. Keep away from heat, sparks and flames. Store locked up.
Specific use(s)	Refer to Section 1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
Benzyl Alcohol	Occupational Exposure Limits have been established by: - Czech Republic - Poland - Latvia
Sodium Hydroxide	Occupational Exposure Limits have been established by: - Austria - Belgium - Switzerland - Czech Republic - Denmark - Estonia - Spain - Finland - France - Greece - Hungary - Ireland - Norway - Poland - Portugal - Sweden - Latvia
Hydrochloric Acid	Occupational Exposure Limits have been established by: - Austria - Belgium - Switzerland - Czech Republic - Denmark - Estonia - Spain - Finland - France - Greece - Hungary - Ireland - Italy - The Netherlands - Norway - Poland - Portugal - Sweden - Latvia
Recommended Industrial Hygiene Monitoring Methods	Contact the Bristol-Myers Squibb AIHA accredited Industrial Hygiene Laboratory at (USA) 732-227-6338. General - The health hazard risk of handling this material is dependent on many factors, including physical form, % API in material being handled, duration and frequency of process task, and effectiveness of controls. If it is necessary to handle this compound outside of engineering controls, an exposure risk assessment should be conducted and procedures documented by a qualified EHS professional.
EXPOSURE CONTROLS / PERSONAL PROTECTION FOR MATERIAL AS SUPPLIED	
This formulation contains an active pharmaceutical ingredient (API) with the guideline limit noted above. To keep the API below the recommended guideline, the material as supplied should be controlled during handling to limit total airborne aerosol exposure to: 25 μg/m³.	
Engineering Controls and Ventilation	FOR MANUFACTURING PROCESSES (BULK): Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. When handling quantities up to 150 milligrams, a standard laboratory with general laboratory dilution ventilation (e.g. 6-12 air changes per hour) is appropriate. When handling quantities from 150 milligrams to 1 kilogram, work in a standard laboratory using a fume hood; biological safety cabinet(Class II, all types); and, approved vented enclosure. Quantities exceeding 1 kilogram should be handled in a designated laboratory using laminar flow/powder containment booth. When handling solutions with low energy operations (pipette transfers, pouring, low velocity stirring, fraction collection, etc.) use protective shielding to limit the spread of splash or splatter. For manufacturing and pilot plant operations, use direct coupling and closed transfer systems for all bulk transfers. Use dust tight valves as appropriate. HEPA filtration of local exhaust ventilation (LEV) is required. FOR CLINICAL SETTING USE (DRUG PRODUCT): When handling small quantities in a clinical setting, good room ventilation is desirable. Specific engineering controls should not be needed.
Respiratory protection	Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. When engineering controls are not sufficient control exposure, wear an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges (EN 140/EN 136) when exposures are up to 10 times the exposure control guideline. Wear a loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator (PAPR) (EN 12941) when exposures are 10-25 times the exposure control guideline. Wear a full facepiece negative pressure respirator with Class 100 or HEPA filters (EN 136) when exposures are 25-50 times the exposure control guideline. Wear a tight-fitting, full facepiece HEPA PAPR (EN 12942) when exposures are 50-100 times the exposure control guideline. Wear a hood-shroud HEPA PAPR (EN 12941) or full facepiece supplied air respirator (EN 139) operated in a pressure demand or other positive pressure mode when exposures are 100-1000 times the exposure control guideline.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
Eye protection	Safety glasses with side-shields are recommended (EN 166). Face shields or chemical safety goggles (EN 166) may be required if splash potential exists or if corrosive materials are present. Note: Choice of eye protection may be influenced by the type of respirator which is selected.
Hand protection	Impervious nitrile, rubber and latex gloves are recommended (EN 420, EN 374). If material is handled in solution, the solvent should also be considered when selecting protective clothing material. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.
Skin and body protection	Wear a laboratory coat (EN 340) when handling quantities up to 1 kilogram. For quantities over 1 kilogram, wear laboratory coat(EN 340)or coverall of low permeability (EN 1149-1). For manufacturing operations, wear coverall of low permeability (EN 465/1149-1). For manufacturing operations, wear coverall of low permeability.
Hygiene	Wash hands and face before breaks and immediately after handling the product.
Environmental exposure controls	Prevent release to drains and waterways.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Thermal/Stability properties	
Autoignition temperature	Not available
Boiling Point	100 °C
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	0 °C
Oxidizing Potential	Not available
Vapor Properties	
Vapor Density	(Air =1): If adequate temperatures caused material to volatize, its vapor density would be much greater than 1. (Heavier than air)
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. STABILITY AND REACTIVITY

Stability	
Chemical Stability	Stable under normal conditions.
Conditions to avoid	Not available
Materials to avoid	Not available
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.: carbon oxides (COx), hydrogen halides
Hazardous reactions	Not available
Sensitivity to static discharge/Dust exp.	
Summary Statements	not applicable

11. TOXICOLOGICAL INFORMATION

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

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

11. TOXICOLOGICAL INFORMATION

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

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

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

11. TOXICOLOGICAL INFORMATION

Benzyl Alcohol

Developmental Toxicity Assessment

Limited data are available.

Human experience

Experiences with Human Exposure

Triamcinolone Acetonide

General effects therapeutic use low exposure - acute effects include: muscle weakness, muscle pain, bone fractures, infection, oedema, headache, difficulty sleeping, vertigo, restlessness, euphoria, mental disturbance, depression, anxiety, mood changes, seizure disorders, nosebleeds, cough, fever, nausea, anaphylaxis, vomiting, anorexia, gastrointestinal disturbance, sore throat, dry mouth, taste disturbance, speech difficulty, congestion, redness and swelling of eyes, vision changes, facial swelling, allergic reactions, skin thinning, acne, redness and swelling of skin, hives, bruising, superficial burning sensation, tingling, increase in blood pressure, Cushing's syndrome, electrolyte disturbance, hyperglycemia, adrenocortical insufficiency, withdrawal symptoms, osteoporosis, bone effects, menstrual irregularities, impaired spermatogenesis, cataracts, glaucoma, nose changes, otitis, peptic ulcer, psychiatric disorders, pancreatitis, changes in white blood cell parameters, alopecia, asthma, growth retardation, skin effects, injection site reactions, cardiac disorders, death.

Benzyl Alcohol

See also symptoms below.

Target Organs

Triamcinolone Acetonide

adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs, male reproductive organs

Benzyl Alcohol

central nervous system

Symptoms

Triamcinolone Acetonide

See "Human Experience".

Benzyl Alcohol

nausea, vomiting, diarrhoea, CNS depression, dizziness, headache, vision changes, rash, redness and swelling of skin, vertigo, delirium

Pharmacokinetics/ Toxicokinetics

Triamcinolone Acetonide

Absorption: Not available

Distribution: Not available

Metabolism: Not available

Elimination: Half-life = 2 - 3 Hour(s) (Human).

11. TOXICOLOGICAL INFORMATION

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

12. ECOLOGICAL INFORMATION

Ecotoxicity effects

Acute Toxicity to Fish

Benzyl Alcohol

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

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

Acute Toxicity to Aquatic Invertebrates

Triamcinolone Acetonide

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

Benzyl Alcohol

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

Toxicity to aquatic plants

Benzyl Alcohol

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

Toxicity to microorganisms

Benzyl Alcohol

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

Mobility Not available

Persistence and degradability

Biodegradation

Triamcinolone Acetonide

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

Benzyl Alcohol

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

Summary Statements

Chemical Fate

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

Not readily biodegradable.

PBT and vPvB assessment Not available

13. DISPOSAL CONSIDERATIONS

Advice On Disposal And Packaging	Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied.
Other information	Disposal by incineration is recommended.

14. TRANSPORT INFORMATION

This material is not a dangerous good for the purpose of transportation in all modes.

15. REGULATORY INFORMATION

United States of America

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

EU Directive 1999/45/EC

BULK MATERIAL

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

DRUG PRODUCT

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

Regulatory Authorizations and Restrictions:	Not available

16. OTHER INFORMATION

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

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

Recommended Restrictions for Use:

Not available

SDS preparation information

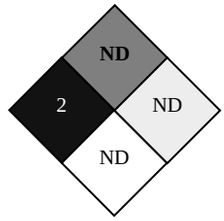
Prepared by	Research and Development Environment, Health and Safety 1-732-227-7380
Prepared on	24.02.2015 DD/MM/YYYY
	This Safety Data Sheet was reformatted in accordance with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) for the United States of America (USA) (CFR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

HMIS

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

NFPA

Health	2
Fire	ND
Reactivity	ND
Special	ND



Country- Specific Emergency Phone Numbers

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

The information contained in this SDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information. and we assume no liability from its use.

SAFETY DATA SHEET

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

Product Identifier

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

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

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

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

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

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

Label Elements

Signal Word: Danger

Hazard Statements:
H360D - May damage the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P314 - Get medical attention/advice if you feel unwell
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

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

Note:

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Ketorolac tromethamine	74103-07-4	Not Listed	Acute Tox.3 (H301) STOT RE 2 (H373) Repr.1A (H360D)	1.5-3.0
Ethanol	64-17-5	200-578-6	Flam. Liq. 2 (H225)	7 - 12
Hydrochloric Acid	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	**
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr.1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

Additional Information:

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

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

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

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

Skin Contact:

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

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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

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

7. HANDLING AND STORAGE

Precautions for Safe Handling

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

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Ethanol

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

Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	2 ppm

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia PEAK	5 ppm 7.5 mg/m^3
Austria OEL - MAKs	5 ppm 8 mg/m^3
Belgium OEL - TWA	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	5 ppm 8.0 mg/m^3
Cyprus OEL - TWA	5 ppm 8 mg/m^3
Czech Republic OEL - TWA	8 mg/m^3
Estonia OEL - TWA	5 ppm 8 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m^3
Germany (DFG) - MAK	2 ppm 3.0 mg/m^3
Greece OEL - TWA	5 ppm 7 mg/m^3
Hungary OEL - TWA	8 mg/m^3
Ireland OEL - TWAs	5 ppm 8 mg/m^3
Italy OEL - TWA	5 ppm 8 mg/m^3
Japan - OELs - Ceilings	2 ppm 3.0 mg/m^3
Latvia OEL - TWA	5 ppm 8 mg/m^3
Lithuania OEL - TWA	5 ppm 8 mg/m^3
Luxembourg OEL - TWA	5 ppm 8 mg/m^3
Malta OEL - TWA	5 ppm 8 mg/m^3
Netherlands OEL - TWA	8 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 ppm 8 mg/m^3
Romania OEL - TWA	5 ppm 8 mg/m^3
Slovakia OEL - TWA	5 ppm 8.0 mg/m^3
Slovenia OEL - TWA	5 ppm 8 mg/m^3
Spain OEL - TWA	5 ppm 7.6 mg/m^3
Switzerland OEL -TWAs	2 ppm 3.0 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3

Sodium hydroxide

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs	2 mg/m^3
Bulgaria OEL - TWA	2.0 mg/m^3
Czech Republic OEL - TWA	1 mg/m^3
Estonia OEL - TWA	1 mg/m^3
France OEL - TWA	2 mg/m^3
Greece OEL - TWA	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Japan - OELs - Ceilings	2 mg/m^3
Latvia OEL - TWA	0.5 mg/m^3
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	0.5 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	1 mg/m^3
Switzerland OEL -TWAs	2 mg/m^3

Sodium chloride

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

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection:	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	**Color:**	Clear to light yellow
Odor:	Alcohol Slight	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
Solubility:	Soluble: Water
pH:	6.9-7.9
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

9. PHYSICAL AND CHEMICAL PROPERTIES

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

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Specific Gravity: 0.991
Viscosity: No data available

Flammablity:
- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** 55 (ethanol)
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
- **Oxidizing Properties:** No data available
- **Conditions to Avoid:** Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: Accidental ingestion may cause effects similar to those seen in clinical use. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

11. TOXICOLOGICAL INFORMATION

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

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

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

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

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

Sodium hydroxide
Mouse IP LD50 40 mg/kg

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

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Ethanol
Eye Irritation Rabbit Severe

Hydrochloric Acid
Skin Irritation Severe
Eye Irritation Severe

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

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

11. TOXICOLOGICAL INFORMATION

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

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

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

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

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

Ethanol
IARC: Group 1 (Carcinogenic to Humans)

Hydrochloric Acid
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:

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

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

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

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

Ketorolac tromethamine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

Ethanol

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

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed

15. REGULATORY INFORMATION

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

Sodium hydroxide

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

Water for injection

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

Sodium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor

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

Revision date: 03-Aug-2016
Product Stewardship Hazard Communication

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

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

End of Safety Data Sheet

SAFETY DATA SHEET

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

Product Identifier

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

Trade Name: Lignocaine Injection
Synonyms: Lidocaine
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product anesthetic agent

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

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

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Lidocaine Hydrochloride	73-78-9	200-803-8	Acute Tox.4 (H302)	1-2
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**

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

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

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

4. FIRST AID MEASURES

Description of First Aid Measures

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

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

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Additional Consideration for Large Spills:	Contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal.

7. HANDLING AND STORAGE

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

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:	Store as directed by product packaging.
Specific end use(s):	Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sodium chloride

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

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit:	2 mg/m^3
Australia PEAK	2 mg/m^3
Austria OEL - MAKs	2 mg/m^3
Bulgaria OEL - TWA	2.0 mg/m^3
Czech Republic OEL - TWA	1 mg/m^3
Estonia OEL - TWA	1 mg/m^3
France OEL - TWA	2 mg/m^3
Greece OEL - TWA	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Japan - OELs - Ceilings	2 mg/m^3
Latvia OEL - TWA	0.5 mg/m^3
OSHA - Final PELS - TWAs:	2 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Poland OEL - TWA	0.5 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	1 mg/m^3
Switzerland OEL -TWAs	2 mg/m^3

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm 7.5 mg/m^3
Austria OEL - MAKs	5 ppm 8 mg/m^3
Belgium OEL - TWA	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	5 ppm 8.0 mg/m^3
Cyprus OEL - TWA	5 ppm 8 mg/m^3
Czech Republic OEL - TWA	8 mg/m^3
Estonia OEL - TWA	5 ppm 8 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m^3
Germany (DFG) - MAK	2 ppm 3.0 mg/m^3
Greece OEL - TWA	5 ppm 7 mg/m^3
Hungary OEL - TWA	8 mg/m^3
Ireland OEL - TWAs	5 ppm 8 mg/m^3
Italy OEL - TWA	5 ppm 8 mg/m^3
Japan - OELs - Ceilings	2 ppm 3.0 mg/m^3
Latvia OEL - TWA	5 ppm 8 mg/m^3
Lithuania OEL - TWA	5 ppm 8 mg/m^3
Luxembourg OEL - TWA	5 ppm 8 mg/m^3
Malta OEL - TWA	5 ppm 8 mg/m^3
Netherlands OEL - TWA	8 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 ppm 8 mg/m^3
Romania OEL - TWA	5 ppm 8 mg/m^3
Slovakia OEL - TWA	5 ppm 8.0 mg/m^3
Slovenia OEL - TWA	5 ppm 8 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA	5 ppm 7.6 mg/m^3
Switzerland OEL -TWAs	2 ppm 3.0 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3

Lidocaine Hydrochloride

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

Sodium chloride

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

Exposure Controls

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

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

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

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

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	**Color:**	Clear, colorless
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

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

9. PHYSICAL AND CHEMICAL PROPERTIES

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

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** No data available
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
- **Oxidizing Properties:** No data available
- **Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

Short Term: Harmful if swallowed May cause mild eye irritation. May cause slight skin irritation. (based on components) Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

Known Clinical Effects: Adverse effects associated with therapeutic use include dizziness, nervousness, agitation, drowsiness, apprehension, euphoria, blurred/double vision, slurred speech, tremors, convulsions, and seizure. Respiratory depression and arrest may follow. Other, more serious effects seen with IV use of this drug, particularly when it is administered rapidly, are cardiovascular collapse, central nervous system depression, and/or hypotension.

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

Lidocaine Hydrochloride

11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 317 mg/kg
Rat Para-periosteal LD50 25mg/kg
Rat Intraperitoneal LD50 133mg/kg
Mouse Oral LD50 292mg/kg
Mouse Intravenous LD50 19.5mg/kg

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

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

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

Lidocaine Hydrochloride
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

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

Lidocaine Hydrochloride

Embryo / Fetal Development	Rat	Subcutaneous	30 mg/kg	NOAEL	Not teratogenic
Embryo / Fetal Development	Rat	Intraperitoneal	56 mg/kg	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Intraperitoneal	72 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Intravenous	500 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Intraperitoneal	6 mg/kg	LOAEL	Developmental toxicity

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

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

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

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

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

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

Lidocaine Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-803-8

Sodium chloride

15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Water for injection

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

SODIUM HYDROXIDE

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

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

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

SAFETY DATA SHEET

Reasons for Revision:	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.
Revision date:	26-Jul-2017
	Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

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

End of Safety Data Sheet

SAFETY DATA SHEET

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.

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SAFETY DATA SHEET

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

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

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Lidocaine Hydrochloride	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate	6108-05-0	$C_{14}H_{22}N_2O$	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.

AKORN

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

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.

AKORN

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.

AKORN

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.

AKORN

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 Does Toxicity

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

Reproduction and Developmental Toxicity

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

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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	*In Vivo* 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.

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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

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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.

SAFETY DATA SHEET

M-M-R II Vaccine

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

SECTION 1. IDENTIFICATION

Product name : M-M-R II Vaccine

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Combustible dust

GHS label elements

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

Other hazards

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 1 - < 5
Neomycin, sulfate (salt)	1405-10-3	< 0.1

SECTION 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact	:	Wash with water and soap. Get medical attention if symptoms occur.
In case of eye contact	:	If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	No special precautions are necessary for first aid responders.
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Metal oxides Chlorine compounds Oxides of phosphorus Phosphorus compounds Nitrogen oxides (NOx)
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment	:	Wear self-contained breathing apparatus for firefighting if nec-

for fire-fighters		essary. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	:	Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labeled containers. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m³	ACGIH
		TWA (Respirable)	5 mg/m³	NIOSH REL
		TWA (total)	10 mg/m³	NIOSH REL
		TWA (total dust)	15 mg/m³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m³	OSHA Z-1
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m3 (OEB 1)	Merck
	Further information: DSEN			
		Wipe limit	0.1 mg/100 cm²	Merck

Engineering measures : Ensure adequate ventilation, especially in confined areas.
Minimize workplace exposure concentrations.
Apply measures to prevent dust explosions.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m3 - total dust, 5 mg/m3 - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m3 - respirable particles, 10 mg/m3 - inhalable particles.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material	:	Chemical-resistant gloves
Remarks	:	For prolonged or repeated contact use protective gloves. Wash hands before breaks and at the end of workday.
Eye protection	:	Wear the following personal protective equipment: Safety goggles
Skin and body protection	:	Skin should be washed after contact.
Hygiene measures	:	Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	No data available
Odor	:	No information available.
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	No data available

Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Dust can form an explosive mixture in air. Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

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

Ingredients:

Sucrose:

Acute oral toxicity	:	LD50 (Rat): 29,700 mg/kg

Neomycin, sulfate (salt):

Acute oral toxicity	:	LD50 (Mouse): 2,880 mg/kg LD50 (Rat): 2,750 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): 633 mg/kg Application Route: Subcutaneous LD50 (Mouse): 116 mg/kg Application Route: Intraperitoneal LD50 (Mouse): 27.6 mg/kg Application Route: Intravenous LD50 (Mouse): 275 mg/kg Application Route: Subcutaneous

Skin corrosion/irritation

Not classified based on available information.

Ingredients:

Neomycin, sulfate (salt):

Species: Rabbit
Result: Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:

Neomycin, sulfate (salt):

Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Ingredients:

Neomycin, sulfate (salt):

Routes of exposure: Dermal
Species: Humans
Result: positive

Germ cell mutagenicity

Not classified based on available information.

Ingredients:

Sucrose:

Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test Result: negative

Neomycin, sulfate (salt):

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	:	Test Type: In vitro mammalian cell gene mutation test Species: Chinese hamster ovary cells Result: negative
	:	Test Type: Chromosomal aberration Species: Human lymphocytes Result: positive
	:	Test Type: in vitro micronucleus test Result: negative
Genotoxicity in vivo	:	Test Type: Cytogenetic assay Species: Mouse Cell type: Bone marrow Application Route: Intravenous injection Result: negative

Carcinogenicity

Not classified based on available information.

Ingredients:

Neomycin, sulfate (salt):

Species: Rat
Exposure time: 2 Years
Result: negative

IARC	No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
NTP	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Ingredients:

Neomycin, sulfate (salt):

Effects on fertility	:	Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity Parent: NOAEL: 25 mg/kg body weight Result: No effects on fertility and early embryonic development were detected.
Effects on fetal development	:	Test Type: Embryo-fetal development Application Route: Oral Embryo-fetal toxicity.: NOAEL: 275 mg/kg body weight Result: No adverse effects., No teratogenic effects. Test Type: Development Application Route: Subcutaneous Developmental Toxicity: LOAEL: 6 mg/kg body weight Result: positive
Reproductive toxicity - Assessment	:	Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Ingredients:

Neomycin, sulfate (salt):

Target Organs: Kidney, inner ear
Assessment: May cause damage to organs through prolonged or repeated exposure.
Remarks: Based on human experience.

Repeated dose toxicity

Ingredients:

Neomycin, sulfate (salt):

Species: Mouse
LOAEL: 30 mg/kg
Application Route: Subcutaneous
Exposure time: 14 d
Target Organs: Kidney

Species: Guinea pig
NOAEL: 50 mg/kg
LOAEL: 100 mg/kg
Application Route: Intramuscular
Exposure time: 30 - 60 Weeks

Target Organs: ear

Species: Guinea pig
NOAEL: 10 mg/kg
Application Route: Oral
Exposure time: 90 d
Remarks: No significant adverse effects were reported

Species: Guinea pig
LOAEL: 100 mg/kg
Application Route: Subcutaneous
Exposure time: 34 d

Species: Dog
NOAEL: 100 mg/kg
Application Route: Oral
Exposure time: 6 Weeks
Remarks: No significant adverse effects were reported

Species: Dog
LOAEL: 24 mg/kg
Application Route: Intramuscular
Exposure time: 30 d
Target Organs: Kidney

Species: Rat
LOAEL: 25 mg/kg
Application Route: oral (feed)
Exposure time: 84 Weeks
Target Organs: ear
Symptoms: hearing loss
Remarks: mortality observed

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Ingredients:

Neomycin, sulfate (salt):

Skin contact	:	Symptoms: Sensitization Remarks: May irritate skin.
Eye contact	:	Remarks: May cause eye irritation.
Ingestion	:	Symptoms: Nausea, Vomiting, Diarrhea, tinnitus, hearing loss, Loss of balance

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Ingredients:

Neomycin, sulfate (salt):

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 72 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 LC50 (Americamysis): 39 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035
Toxicity to algae	:	EC50 (Anabaena flos-aquae (cyanobacterium)): 0.00075 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0003 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 EC50 (Pseudokirchneriella subcapitata (green algae)): 0.0099 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0022 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1,000
M-Factor (Chronic aquatic toxicity)	:	10
Toxicity to microorganisms	:	EC50 (Natural microorganism): 107.6 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 EC10 (Natural microorganism): 2.8 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

Ingredients:

Neomycin, sulfate (salt):

Biodegradability	:	Result: rapidly degradable Biodegradation: 50 % Exposure time: 1.2 d Method: OECD Test Guideline 314

Bioaccumulative potential

Ingredients:

Sucrose:

Partition coefficient: n-octanol/water	:	Pow: < 1

Neomycin, sulfate (salt):

Partition coefficient: n-octanol/water	:	log Pow: < -2

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt))
Class	:	9
Packing group	:	III
Labels	:	9

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Neomycin, sulfate (salt))
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous

Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956

IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt))
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

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

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Neomycin, sulfate (salt))
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	yes(Neomycin, sulfate (salt))
Remarks	:	Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

Ingredients	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Disodium hydrogenorthophosphate	7558-79-4	5000	90909

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Fire Hazard

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

US State Regulations

Pennsylvania Right To Know

D-Glucitol	50-70-4
Gelatins	9000-70-8
Sodium chloride	7647-14-5
Sodium phosphate, monobasic	7558-80-7
Disodium hydrogenorthophosphate	7558-79-4
Sucrose	57-50-1

California Prop. 65

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

Neomycin, sulfate (salt)	1405-10-3

California List of Hazardous Substances

Disodium hydrogenorthophosphate	7558-79-4

California Permissible Exposure Limits for Chemical Contaminants

Sucrose	57-50-1

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

AICS : not determined

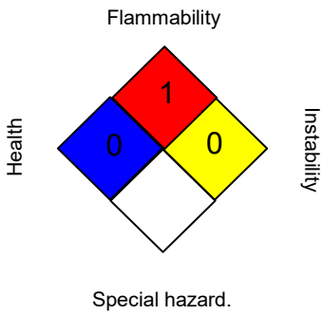
DSL : not determined

IECSC : not determined

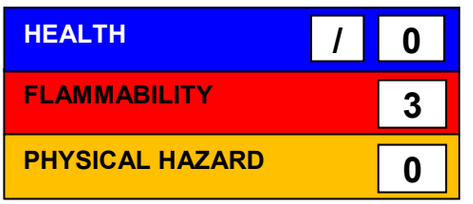
SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Revision Date	:	04/13/2017

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a

guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

US / Z8

Hospira

SAFETY DATA SHEET

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

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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

2. HAZARD(S) IDENTIFICATION

Emergency Overview

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

U.S. OSHA GHS Classification

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

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

Label Element(s)

Pictogram	NA
Signal Word	NA
Hazard Statement(s)	NA
Precautionary Statement(s) Prevention	Do not breathe vapor or spray Wash hands thoroughly after handling
Response	Get medical attention if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

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

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

4. FIRST AID MEASURES

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

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

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

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

5. FIRE FIGHTING MEASURES

Flammability None anticipated for this aqueous product.

Fire & Explosion Hazard None anticipated for this aqueous product.

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

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

6. ACCIDENTAL RELEASE MEASURES

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

7. HANDLING AND STORAGE

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

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

Special Precautions No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

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

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

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

9. PHYSICAL/CHEMICAL PROPERTIES

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

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

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

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

LD 50: Dosage that produces 50% mortality.

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

11. TOXICOLOGICAL INFORMATION: continued

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

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORTATION INFORMATION

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

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

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

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

GHS/CLP Classification*

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

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

Prevention

Do not breathe vapor or spray
Wash hands thoroughly after handling

Response

Get medical attention if you feel unwell.

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

EU Classification*

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

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

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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SDS DATE: 11/11/2015___

SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: McKesson Bacitracin ointment

MFR #: 1175

DISTRIBUTED BY:

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

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

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

PRODUCT DESCRIPTION: First Aid Antibiotic

SECTION 2: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: Topical

POTENTIAL HEALTH EFFECTS: This is a pharmaceutical material available without a prescription- use only as directed. See product packaging for further information concerning adverse effects and drug interaction precautions.

EYES: May cause irritation with symptoms of reddening, tearing and stinging

SKIN: Allergy to any ingredient may cause anaphylactic shock

INGESTION: Symptoms of ingestion may include abdominal pain, nausea, vomiting, and diarrhea.

INHALATION: N/A

ACUTE HEALTH HAZARDS: No data available for this product.

CHRONIC HEALTH HAZARDS: N/A

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: Pre-existing skin conditions may be aggravated by repeated overexposures to this product.

CARCINOGENICITY

OSHA: Not Listed **ACGIH:** Not Listed **NTP:** Not Listed **IARC:** Not Listed
OTHER: N/A

SECTION 2 NOTES: The components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

SECTION 3: COMPOSITION/ INFORMATION OF INGREDIENTS

INGREDIENT	CAS NO.	%	Exposure Limits
Petrolatum	8009-03-8	10-100	N/A
Bacitracin Zinc	1405-89-6	0.1-1	LD50 (oral mouse) >3750 mg/kg LD50 (oral Guinea pig) 2gm/kg

SECTION 3 NOTES: The formulations for these products are proprietary information. Inactive ingredients of less than 1% not displayed above.

SECTION 4: FIRST-AID MEASURES

EYES: In case of contact, flush with copious amounts of water for at least 15 minutes. Call a physician.

SKIN: N/A

INGESTION: In case of accidental ingestion, contact your regional poison center or physician immediately.

INHALATION: N/A

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure.

SECTION 4 NOTES: N/A

SECTION 5: FIRE-FIGHTING MEASURES

FLAMMABLE LIMITS IN AIR, UPPER: Not Established
(% BY VOLUME) LOWER: Not Established

FLASH POINT: Not established

METHOD USED: N/A

AUTOIGNITION TEMPERATURE: Not Established

NFPA HAZARD CLASSIFICATION

HEALTH:	1	FLAMMABILITY:	1	REACTIVITY:	0	OTHER:	N/A

HMIS HAZARD CLASSIFICATION

HEALTH:	2	FLAMMABILITY:	1	REACTIVITY:	N/A	PERSONAL:	0

EXTINGUISHING MEDIA: Water Fog, Sand, Earth, Dry Chemical, Foam

SPECIAL FIRE FIGHTING PROCEDURES: Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes

UNUSUAL FIRE AND EXPLOSION HAZARDS: This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, and sulfur oxides).

HAZARDOUS DECOMPOSITION PRODUCTS: None known

SECTION 5 NOTES: See section 9 for physical and chemical properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: Scrape or shovel material. Use oil absorbent rags. Use appropriate personal protective equipment during clean up.

SECTION 6 NOTES: See Sections 9 and 10 for additional physical, chemical and hazard information.

SECTION 7: HANDLING AND STORAGE

HANDLING: Keep this and all drugs out of the reach of children. Avoid contact with eyes.

STORAGE: Store in a dry place away from excessive heat, in original or similar waterproof containers. Use normal precautions for storage of drug.

OTHER PRECAUTIONS: N/A

SECTION 7 NOTES: This product is a human pharmaceutical. Follow all industry standards for use of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

VENTILATION: None necessary when used as intended.

RESPIRATORY PROTECTION: None necessary when used as intended.

EYE PROTECTION: None necessary when used as intended.

SKIN PROTECTION: None necessary when used as intended.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

WORK HYGIENIC PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration.

EXPOSURE GUIDELINES: Not established

SECTION 8 NOTES: The following guidance applies to the handling of the active ingredient(s) in this formulation. The end-user should perform an appropriate risk assessment when handling other forms or formulations of this active ingredient.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Nearly odorless, yellow to off white

PHYSICAL STATE: ointment

pH AS SUPPLIED: Not established
pH (Other): Not established
BOILING POINT: > 200°C
MELTING POINT: Not established
FREEZING POINT: Not established
VAPOR PRESSURE (mmHg): Not established
DENSITY (lb/gal): N/A
@ N/A
SPECIFIC GRAVITY (H2O = 1): 0.8
EVAPORATION RATE: Not established

BASIS (=1): N/A

SOLUBILITY IN WATER: Not soluble

PERCENT SOLIDS BY WEIGHT: Not established

PERCENT VOLATILE: Not established
BY WT/ N/A **BY VOL @** N/A

VOLATILE ORGANIC COMPOUNDS (VOC): Not established

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

MOLECULAR WEIGHT: Not established

VISCOSITY: Not established

SECTION 9 NOTES: See Section 5 for flammability/explosivity information.

SECTION 10: STABILITY AND REACTIVITY

	STABLE	UNSTABLE
STABILITY:	X	

CONDITIONS TO AVOID (STABILITY): Avoid heat, light, and contact with incompatible chemicals.

INCOMPATIBILITY (MATERIAL TO AVOID): Oxidizing agents

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: None known.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID (POLYMERIZATION): N/A

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: No data available for this product.

SECTION 11 NOTES: The information below pertains to the formulated product unless indicated otherwise.

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: This product has not been tested for Eco toxicity.

SECTION 12 NOTES: There is no environmental data available for this product.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incarceration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

RCRA HAZARD CLASS: Not available

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION
- **PROPER SHIPPING NAME:** N/A
- **HAZARD CLASS:** N/A
- **DOT SHIPPING ID NUMBER:** N/A
- **DOT PACKING GROUP:** N/A
- **DOT HAZARD CLASS:** N/A
- **DOT LABEL STATEMENT:** N/A

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

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

SECTION 14 NOTES: This material is not subject to the transportation regulations of DOT, IATA, and the ADR.

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TSCA (TOXIC SUBSTANCE CONTROL ACT): Exempt
CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): Not Listed

SARA 311/312 HAZARD CATEGORIES: Exempt
SARA 313 REPORTABLE INGREDIENTS: Contains NO hazardous ingredients subject to reporting requirements of Section 313 of SARA Title II.

STATE REGULATIONS: The components of this product are not on the California Proposition 65 lists.

INTERNATIONAL REGULATIONS: Not applicable.

SECTION 15 NOTES: For details on your regulatory requirements you should contact the appropriate agency in your state.

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A

PREPARATION INFORMATION:

SDS CREATION DATE: November 11, 2015
SDS VERSION: Original

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

McKESSON

SDS DATE: 10/29/15

SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

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

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

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

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

PRODUCT DESCRIPTION: McKesson Hydrogen Peroxide, 3%

SECTION 2: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: N/A

POTENTIAL HEALTH EFFECTS:

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

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

INGESTION: N/A

INHALATION: N/A

ACUTE HEALTH HAZARDS: N/A

CHRONIC HEALTH HAZARDS: N/A

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: N/A

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

SECTION 2 NOTES:

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

Label elements

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

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

[Prevention]:

P260 Do not breathe mist / vapors / spray.

P264 Wash thoroughly after handling.

P280 Wear protective gloves / eye protection / face protection.

[Response]:

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

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

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

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

P310 Immediately call a POISON CENTER or doctor / physician.

P363 Wash contaminated clothing before reuse.

[Storage]:

P405 Store locked up.

[Disposal]:

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

SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS

INGREDIENT	CAS NO.	%	Exposure Limits

SECTION 3 NOTES:

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

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

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

SECTION 4: FIRST-AID MEASURES

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

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

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

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

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

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: N/A

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

Most important symptoms and effects, both acute and delayed

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

SECTION 5: FIRE-FIGHTING MEASURES

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

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

AUTOIGNITION TEMPERATURE: N/A

NFPA HAZARD CLASSIFICATION

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

HMIS HAZARD CLASSIFICATION

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

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

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

UNUSUAL FIRE AND EXPLOSION HAZARDS: N/A

HAZARDOUS DECOMPOSITION PRODUCTS: Oxygen which supports combustion.

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

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: N/A

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

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

Environmental precautions

Biodegradable, non-hazardous to environment.

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

Methods and material for containment and cleaning up.

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

SECTION 7: HANDLING AND STORAGE

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

STORAGE: Handle containers carefully to prevent damage and spillage.

Incompatible materials: Reducing agents, combustible materials.

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

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

OTHER PRECAUTIONS: N/A

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: N/A

VENTILATION:

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

EYE PROTECTION: Protective goggles if desired.

SKIN PROTECTION: Rubber or vinyl gloves.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

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

EXPOSURE GUIDELINES:

SECTION 8 NOTES: N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Clear, colorless, odorless liquid

PHYSICAL STATE: N/A

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

@ N/A
EVAPORATION RATE: >1

BASIS (=1): N/A

SOLUBILITY IN WATER: Complete

PERCENT SOLIDS BY WEIGHT: N/A

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

VOLATILE ORGANIC COMPOUNDS (VOC): N/A

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

MOLECULAR WEIGHT: N/A

VISCOSITY: N/A

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

SECTION 10: STABILITY AND REACTIVITY

STABLE **UNSTABLE**

STABILITY: Stable under normal conditions.

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

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

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

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID (POLYMERIZATION): N/A

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

Acute Toxicity

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

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

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

SECTION 11 NOTES: N/A

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:

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

Aquatic Ecotoxicity

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

Persistence and degradability

There is no data available on the preparation itself.

Bioaccumulative potential

Not Measured

Mobility in soil

No data available.

Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

Other adverse effects

No data available.

SECTION 12 NOTES: N/A

SECTION 13: DISPOSAL CONSIDERATIONS

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

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

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

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

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

SECTION 14 NOTES: N/A

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

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

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

EPCRA 301 Extremely Dangerous: Hydrogen Peroxide

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

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

STATE REGULATIONS:

New Jersey RTK Substances (>1%):

Hydrogen peroxide

Pennsylvania RTK Substances (>1%):

Hydrogen peroxide

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

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

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

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

No chemicals at levels which require reporting under this statute.

INTERNATIONAL REGULATIONS: N/A

SECTION 15 NOTES: N/A

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A

PREPARATION INFORMATION: N/A

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

SDS DATE: 8/7/2015

SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

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

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

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

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

PRODUCT DESCRIPTION: Alcohol, Isopropyl 70%

SECTION 2: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: N/A

POTENTIAL HEALTH EFFECTS: N/A

EYES: N/A

SKIN: N/A

INGESTION:N/A

INHALATION: N/A

ACUTE HEALTH HAZARDS: N/A

CHRONIC HEALTH HAZARDS: N/A

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: N/A

CARCINOGENICITY

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

OTHER: N/A

SECTION 2 NOTES:

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

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

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

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

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

Storage
P403+233 Store in a well ventilated place. Keep container tightly closed.
P405 Store locked up.

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

SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS

INGREDIENT	CAS NO.	%	Exposure Limits
Isopropyl Alcohol	67-63-0	50-75	OSHA TWA 400 ppm (980mg/m3)STEL 500 ppm ACGIH TWA: 200 ppm STEL: 400 ppm Revised 2003, NIOSH TWA 400 ppm (980 mg/m3) ST 500 ppm (1225 mg/m3)

SECTION 3 NOTES:

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

Substance classified with a health or environmental hazard.

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

SECTION 4: FIRST-AID MEASURES

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

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

INGESTION: If swallowed obtain immediate medical attention. Keep at rest. Do NOT induce vomiting.

INHALATION: Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:

SECTION 4 NOTES: N

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

Most important symptoms and effects, both acute and delayed
Overview Signs and Symptoms of Exposure: Giddiness, headache, dizziness and nausea.

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

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

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

Not a carcinogen.

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

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

Inhalation May cause drowsiness or dizziness.

Eyes Causes serious eye irritation.

SECTION 5: FIRE-FIGHTING MEASURES

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

FLASH POINT: 77 F
METHOD USED: TCC

AUTOIGNITION TEMPERATURE: N/A

NFPA HAZARD CLASSIFICATION

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

HMIS HAZARD CLASSIFICATION

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

SPECIAL FIRE FIGHTING PROCEDURES:

UNUSUAL FIRE AND EXPLOSION HAZARDS:

HAZARDOUS DECOMPOSITION PRODUCTS:

SECTION 5 NOTES:

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

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

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES:

SECTION 6 NOTES:

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

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

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

SECTION 7: HANDLING AND STORAGE

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

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

OTHER PRECAUTIONS: N/A

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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

VENTILATION:

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

EYE PROTECTION: Protective goggles if desired.

SKIN PROTECTION: Rubber or vinyl gloves if desired.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

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

EXPOSURE GUIDELINES: N/A

SECTION 8 NOTES:

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Colorless Liquid, Characteristic

PHYSICAL STATE:

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

BASIS (=1): N/A

SOLUBILITY IN WATER: Complete

PERCENT SOLIDS BY WEIGHT: N/A

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

VOLATILE ORGANIC COMPOUNDS (VOC): N/A

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

MOLECULAR WEIGHT: N/A

VISCOSITY: Not Measured

SECTION 9 NOTES: N/A

SECTION 10: STABILITY AND REACTIVITY

STABLE **UNSTABLE**

STABILITY: Stable under normal conditions.

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

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

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

HAZARDOUS POLYMERIZATION: N/A

CONDITIONS TO AVOID (POLYMERIZATION): N/A

SECTION 10 NOTES:
Reactivity
Hazardous Polymerization will not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

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

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

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

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

SECTION 11 NOTES:

SECTION 12: ECOLOGICAL INFORMATION

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

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

SECTION 12 NOTES:
Persistence and degradability:There is no data available on the preparation itself.
Bioaccumulative potential: Not Measured
Mobility in soil:No data available.

Results of PBT and vPvB assessment:This product contains no PBT/vPvB chemicals.
Other adverse effects: No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

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

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

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

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

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

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

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS
TSCA (TOXIC SUBSTANCE CONTROL ACT): All components of this material are either listed or exempt from listing on the TSCA inventory.
CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): N/A

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

SARA 313 REPORTABLE INGREDIENTS: Isopropyl Alcohol

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

INTERNATIONAL REGULATIONS: WHMIS: B2 D2B

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

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A

PREPARATION INFORMATION: N/A

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

SDS DATE: 9/18/2015

SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: McKesson Premium Instant Hand Sanitizer
MFR #: 53-28032-4, 53-28033-8, 53-28035-1000, 53-28037-18

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

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

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

PRODUCT DESCRIPTION: A gelled alcohol hand sanitizer for hand washing to decrease bacteria on the skin

2. HAZARDS IDENTIFICATION

Classification

Flammable Liquids	Category 2

Signal Word
Danger

Hazard Statements
Highly flammable liquid and vapor

Appearance: Clear blue gel **Physical State** Gel **Odor** Alcohol

Precautionary Statements - Prevention
Keep away from heat/sparks/open flames/hot surfaces. — No smoking
Keep container tightly closed
Ground/bond container and receiving equipment
Use explosion-proof equipment
Use only non-sparking tools
Take precautionary measures against static discharge
Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response
IN CASE OF FIRE: Use CO2, dry chemical, or foam for extinction

Precautionary Statements - Storage
Store in a well-ventilated place

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal plant

Other Hazards
Toxic to aquatic life with long lasting effects

McKESSON

SDS DATE: 9/18/2015

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%
Ethanol	64-17-5	70

4. FIRST-AID MEASURES

First Aid Measures

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Skin Contact If skin irritation occurs, rinse affected area with water.

Inhalation Remove to fresh air.

Ingestion Dilute by giving a large amount of water. Call a physician or Poison Control Center.

Most important symptoms and effects

Symptoms Exposed individuals may experience eye tearing, redness and discomfort. May cause gastrointestinal disturbance. Inhalation may cause giddiness or loss of consciousness.

Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media
Carbon dioxide (CO2). Alcohol resistant foam. Dry chemical.

Unsuitable Extinguishing Media Not determined.

Specific Hazards Arising from the Chemical
Vapors may travel to source of ignition and flash back. Alcohol flames may be difficult to see; the flames are virtually colorless.

Hazardous Combustion Products Carbon oxides.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Use personal protective equipment as required.

Environmental Precautions See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

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

Methods for Clean-Up

Small spills (less than 1 gallon) may be washed down a drain with lots of water or cleaned up and disposed of into a sanitary sewer system.
Large spills (more than 1 gallon) should be contained and collected (by absorption [sand, clay, or other absorbent material] or vacuuming) then disposed of properly.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on Safe Handling

Keep away from heat/sparks/open flames/hot surfaces. — No smoking. Use spark-proof tools and explosion-proof equipment. Ground/bond container and receiving equipment. Take precautionary measures against static discharges.

Conditions for safe storage, including any incompatibilities

Storage Conditions

Keep containers tightly closed in a dry, cool and well-ventilated place. Do not contaminate food or feed stuffs. Do not reuse container. Keep out of the reach of children.

Incompatible Materials

Strong oxidizers. Hydrogen peroxide. Bromine. Chromic acid.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Ethanol 64-17-5	STEL: 1000 ppm	TWA: 1000 ppm TWA: 1900 mg/m^3 (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m^3	IDLH: 3300 ppm TWA: 1000 ppm TWA: 1900 mg/m^3

Glycerol 56-81-5	TWA: 10 mg/m^3 mist	TWA: 15 mg/m^3 mist, total particulate TWA: 5 mg/m^3 mist, respirable fraction (vacated) TWA: 10 mg/m^3 mist, total particulate (vacated) TWA: 5 mg/m^3 mist, respirable fraction	-
Isopropyl alcohol 67-63-0	STEL: 400 ppm TWA: 200 ppm	TWA: 400 ppm TWA: 980 mg/m^3 (vacated) TWA: 400 ppm (vacated) TWA: 980 mg/m^3 (vacated) STEL: 500 ppm (vacated) STEL: 1225 mg/m^3	IDLH: 2000 ppm TWA: 400 ppm TWA: 980 mg/m^3 STEL: 500 ppm STEL: 1225 mg/m^3

Appropriate engineering controls

Engineering Controls Apply technical measures to comply with the occupational exposure limits. Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/Face Protection Avoid contact with eyes.

Skin and Body Protection No special technical protective measures are necessary.

Respiratory Protection No protective equipment is needed under normal use conditions.

General Hygiene Considerations Do not get in eyes. Keep away from food and drink.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Gel		
Appearance	Clear blue gel	**Odor**	Alcohol
Color	blue	**Odor Threshold**	Not determined

Property	**Values**	**Remarks • Method**
pH	6.00-8.00	
Melting Point/Freezing Point	Not established	
Boiling Point/Boiling Range	100 °C / 212 °F	
Flash Point	21 °C / 70 °F	SETA
Evaporation Rate	Not established	
Flammability (Solid, Gas)	Not determined	
Upper Flammability Limits	Not determined	
Lower Flammability Limit	Not determined	
Vapor Pressure	Not established	
Vapor Density	Not established	
Specific Gravity	.858 - .882	
Water Solubility	Completely soluble	
Solubility in other solvents	Not determined	
Property	**Values**	**Remarks • Method**
Partition Coefficient	Not determined	
Autoignition Temperature	Not determined	
Decomposition Temperature	Not determined	
Kinematic Viscosity	Not determined	
Dynamic Viscosity	6000-10000 cps	
Explosive Properties	Not determined	

Oxidizing Properties	Not determined
Density	7.15-7.35 lb/gal

10. STABILITY AND REACTIVITY

Reactivity
Not reactive under normal conditions.

Chemical Stability
Stable under recommended storage conditions.

Possibility of Hazardous Reactions
None under normal processing.

Hazardous Polymerization Hazardous polymerization does not occur.

Conditions to Avoid
Keep out of reach of children.

Incompatible Materials
Strong oxidizers. Hydrogen peroxide. Bromine. Chromic acid.

Hazardous Decomposition Products
Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Eye Contact Avoid contact with eyes.

Skin Contact Not expected to be a skin irritant during prescribed use.

Inhalation Avoid breathing vapors or mists.

Ingestion Do not taste or swallow.

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Ethanol 64-17-5	= 7060 mg/kg (Rat)	-	= 124.7 mg/L (Rat) 4 h
Carbomer 9003-01-4	= 2500 mg/kg (Rat)	-	-
Glycerol 56-81-5	= 12600 mg/kg (Rat)	> 21900 mg/kg (Rat)	-
Isopropyl alcohol 67-63-0	= 4396 mg/kg (Rat)	= 12800 mg/kg (Rat) = 12870 mg/kg (Rabbit)	= 72.6 mg/L (Rat) 4 h
Isopropyl Myristate 110-27-0	> 10000 mg/kg (Rat)	= 5 g/kg (Rabbit)	> 41 mg/L (Rat)
Propylene Glycol 25322-69-4	> 2 g/kg (Rat)	-	-

Information on physical, chemical and toxicological effects

Symptoms Please see section 4 of this SDS for symptoms.

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

Carcinogenicity

Isopropyl Alcohol (IPA) is listed as an IARC Monograph Group 3 chemical. However, IARC Group 3 chemicals are "not classifiable as human carcinogens". IPA is classified as an IARC Group 1 chemical ONLY when manufactured by the strong-acid process. The IPA used in this product is NOT manufactured by the strong-acid process and is therefore not classifiable as a human carcinogen. Ethanol has been shown to be carcinogenic in long-term studies only when consumed as an alcoholic beverage.

Chemical Name	ACGIH	IARC	NTP	OSHA
Ethanol 64-17-5	A3	Group 1	Known	X

Legend

ACGIH (American Conference of Governmental Industrial Hygienists)
A3 - Animal Carcinogen
IARC (International Agency for Research on Cancer)
Group 1 - Carcinogenic to Humans
Group 3 IARC components are "not classifiable as human carcinogens"
NTP (National Toxicology Program)
Known - Known Carcinogen
OSHA (Occupational Safety and Health Administration of the US Department of Labor)
X - Present

Numerical measures of toxicity

Not determined

12. ECOLOGICAL INFORMATION

Ecotoxicity

Toxic to aquatic life with long lasting effects.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Ethanol 64-17-5		12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static 100: 96 h Pimephales promelas mg/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through		9268 - 14221: 48 h Daphnia magna mg/L LC50 10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static
Carbomer 9003-01-4		580: 96 h Lepomis macrochirus mg/L LC50		168: 96 h water flea mg/L EC50
Glycerol 56-81-5		51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static		500: 24 h Daphnia magna mg/L EC50
Isopropyl alcohol 67-63-0	1000: 96 h Desmodesmus subspicatus mg/L EC50 1000: 72 h Desmodesmus subspicatus mg/L EC50	9640: 96 h Pimephales promelas mg/L LC50 flow-through 11130: 96 h Pimephales promelas mg/L LC50 static 1400000: 96 h Lepomis macrochirus µg/L LC50		13299: 48 h Daphnia magna mg/L EC50
Isopropyl Myristate 110-27-0	100: 72 h Desmodesmus subspicatus mg/L EC50	8400: 96 h Brachydanio rerio mg/L LC50 semi-static 8400: 96 h Brachydanio rerio mg/L LC50		100: 48 h Daphnia magna mg/L EC50

Persistence/Degradability

Not determined

Bioaccumulation

Not determined

Mobility

Chemical Name	Partition Coefficient

Ethanol 64-17-5	-0.32

Other Adverse Effects
Not determined

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods

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

Contaminated Packaging Disposal should be in accordance with applicable regional, national and local laws and regulations.

California Hazardous Waste Status

Chemical Name	California Hazardous Waste Status
Ethanol 64-17-5	Toxic Ignitable

14. TRANSPORT INFORMATION

Note This product as packaged in 4oz, 8oz, 18oz & 1000mL is shipped as Limited Quantity

DOT
UN/ID No UN1170
Proper Shipping Name Ethanol solution
Hazard Class 3
Packing Group II

IATA
UN/ID No UN1170
Proper Shipping Name Ethanol solution
Hazard Class 3
Packing Group II

IMDG
UN/ID No UN1170
Proper Shipping Name Ethanol solution
Hazard Class 3
Packing Group II

15. REGULATORY INFORMATION

International Inventories
Not determined

US Federal Regulations

SARA 313

Chemical Name	CAS No	Weight-%	SARA 313 - Threshold Values %
Isopropyl alcohol - 67-63-0	67-63-0	0.25	1.0

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals.

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

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Ethanol 64-17-5	X	X	X
Glycerol 56-81-5	X	X	X
Isopropyl alcohol 67-63-0	X	X	X

16. OTHER INFORMATION

NFPA	**Health Hazards**	**Flammability**	**Instability**	**Special Hazards**
	Not determined	Not determined	Not determined	Not determined
HMIS	**Health Hazards**	**Flammability**	**Physical Hazards**	**Personal Protection**
	0	3	0	0

Issue Date 23-JUN-2013
Revision Date: 18-SEP-2015
Revision Note New format

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

SANOFI PASTEUR

US - OSHA SAFETY DATA SHEET

Issue Date 16-Apr-2015 **Revision Date** **Version** 1

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

Product identifier

Product Name **Menactra®**

Other means of identification

Product Information Single dose vial (NDC 49281-589-58)
Supplied as a package of 5 vials (NDC 49281-589-05)

Synonyms Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine

Recommended use of the chemical and restrictions on use

Recommended Use Active immunization to prevent invasive meningococcal disease caused by *N meningitides* serogroups A, C, Y and W-135.

Uses advised against Not available.

Details of the supplier of the safety data sheet

Supplier Address
Sanofi Pasteur
1 Discovery Drive
Swiftwater, PA 18370

Emergency telephone number

Company Phone Number 1-800-VACCINE (1-800-822-2463)
24 Hour Emergency Phone Number 1-570-957-4400
Emergency Telephone 1-570-957-4400

2. HAZARDS IDENTIFICATION

Classification

Health Hazards
Not classified.

Physical hazards
Not classified.

OSHA Regulatory Status
This product is a vaccine that is safe for consumers when used according to the label directions. Potential hazards that may occur if product is not used according to the consumer label are as follows throughout the sheet.

Label elements

Emergency Overview

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

Appearance Clear to slightly turbid solution. **Physical state** Liquid **Odor** Not available.

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine

Chemical Name	CAS No.	Weight-%
Meningococcal (Serogroup A) Polysaccharide (Monovalent Conjugate)	N/A	0.008
Meningococcal (Serogroup C) Polysaccharide (Monovalent Conjugate)	N/A	0.008
Meningococcal (Serogroup Y) Polysaccharide (Monovalent Conjugate)	N/A	0.008
Meningococcal (SerogroupW135) Polysaccharide (Monovalent Conjugate)	N/A	0.008
Diphtheria Toxoid Protein	N/A	0.0096
Sodium Chloride	7647-14-5	0.87
Water	7732-18-5	q.s. to 100

Note: Ingredients below reportable levels are not listed.

4. FIRST AID MEASURES

First aid measures

Eye contact In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin Contact In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

Inhalation In case of inhalation, remove to fresh air. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention if needed. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Self-protection of the first aider Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms Common effects of vaccine for infants and toddlers 9 and 12 months of age were injection site tenderness, erythema, and swelling; irritability, abnormal crying, drowsiness, appetite loss, vomiting, and fever.

Common effects of the vaccine for individuals 2 through 55 years of age were injection site pain, redness, induration and swelling; anorexia, diarrhea, irritability, drowsiness, headache, fatigue, malaise, and arthralgia.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

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

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical

Not available.

Hazardous combustion products Not available.

Explosion data
Sensitivity to Mechanical Impact Not available.
Sensitivity to Static Discharge None known.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
Personal precautions Wear appropriate personal protective equipment (see Section 8).

Environmental precautions
Environmental precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up
Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Wipe up with absorbent material (e.g. cloth) for disposal. Area where spill occurred can be cleaned with the regular cleaning materials designated for the area.

7. HANDLING AND STORAGE

Precautions for safe handling
Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities
Storage Conditions Store at 2° to 8°C (35° to 46°F). Do not freeze.

Incompatible materials Not available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters
Exposure Guidelines This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region specific regulatory bodies.

Appropriate engineering controls
Engineering Controls Used as supplied, no special engineering controls are needed when administering the vaccine.

Individual protection measures, such as personal protective equipment
Eye/face protection In laboratory or industrial settings, safety glasses with side shields are recommended.

Skin and body protection In laboratory or industrial settings, gloves and lab coats are recommended.

Respiratory protection Used as supplied, general room ventilation is acceptable and no special respiratory protection is needed when administering the vaccine.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid		
Appearance	Clear to slightly turbid solution.	**Odor**	Not available.
Color	Clear	**Odor threshold**	Not available.

Property	**Values**	**Remarks**
pH	Not available.	
Melting point/freezing point	Not available.	
Boiling point / boiling range	Not available.	
Flash point	Not available.	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	Not available.	
Lower flammability limit:	Not available.	
Vapor pressure	Not available.	
Vapor density	Not available.	
Specific Gravity	Not available.	
Water solubility	Not available.	
Solubility in other solvents	Not available.	
Partition coefficient	Not available.	
Autoignition temperature	Not available.	
Decomposition temperature	Not available.	
Kinematic viscosity	Not available.	
Dynamic viscosity	Not available.	
Explosive properties	Not available.	
Oxidizing properties	Not available.	

Other Information

Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk density	Not available.

10. STABILITY AND REACTIVITY

Reactivity
Not reactive under normal conditions.

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal handling.

Hazardous polymerization Hazardous polymerization does not occur.

Conditions to avoid
Not available.

Incompatible materials
Not available.

Hazardous Decomposition Products
None under normal use conditions.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information	No data available.
Inhalation	No impact known or expected under normal use.
Eye contact	No impact known or expected under normal use.
Skin Contact	No impact known or expected under normal use.
Ingestion	No impact known or expected under normal use.

Information on toxicological effects

Symptoms	Common effects of vaccine for infants and toddlers 9 and 12 months of ager were injection site tenderness, erythema, and swelling; irritability, abnormal crying, drowsiness, appetite loss, vomiting, and fever. Common effects of the vaccine for individuals 2 through 55 years of age were injection site pain, redness, induration and swelling; anorexia, diarrhea, irritability, drowsiness, headache, fatigue, malaise, and arthralgia.

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

Skin corrosion/irritation	Not available.
Serious eye damage/eye irritation	Not available.
Irritation	Not available.
Corrosivity	Not available.
Sensitization	Not available.
Germ cell mutagenicity	Menactra vaccine has not been evaluated for mutagenic potential.
Carcinogenicity	Menactra vaccine has not been evaluated for carcinogenic potential.
Reproductive toxicity	Pregnancy Category C Animal reproduction studies have not been conducted with Menactra vaccine. It is also not known whether Menactra vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. There are no adequate and well controlled studies in pregnant women. Menactra vaccine should only be given to a pregnant woman if clearly needed. Assessment of the effects on animal reproduction has not been fully conducted with Menactra vaccine as effects on male fertility in animals as not been evaluated. The effect of Menactra vaccine on embryo-fetal and pre-weaning development was evaluated in one developmental toxicity study in mice. Animals were administered Menactra vaccine on Day 14 prior to gestation and during the period of organogenesis (gestation Day 6). The total dose given per time point was 0.1 mL/mouse via intramuscular injection (900 times the human dose, adjusted by body weight). There were no adverse effects on pregnancy, parturition, lactation or pre-weaning development noted in this study. Skeletal examinations revealed one fetus (1 of 234 examined) in the vaccine group with a cleft palate. None were observed in the concurrent control group (0 of 174 examined). There are no data that suggest that this isolated finding is vaccine-related, and there were no vaccine-related fetal malformations or other evidence of teratogenesis observed in this study. It is not known whether Menactra vaccine is excreted in human milk.
Developmental Toxicity	Not available.
Teratogenicity	Not available.
STOT - single exposure	Not classified.
STOT - repeated exposure	Not classified.
Chronic toxicity	Not available.
Subchronic toxicity	Not available.
Target Organ Effects	Not available.
Neurological effects	Not available.
Other adverse effects	Not available.

Aspiration hazard Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity
Not available.

Persistence and degradability
Not available.

Bioaccumulation
Not available.

Mobility
Not available.

Other adverse effects Not available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

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

Contaminated packaging Disposal should be in accordance with applicable regional, national and local laws and regulations.

US EPA Waste Number Not applicable.

California Hazardous Waste Codes Not applicable.

14. TRANSPORT INFORMATION

DOT Not regulated.

TDG Not regulated.

MEX Not regulated.

ICAO (air) Not regulated.

IATA Not regulated.

IMDG Not regulated.

RID Not regulated.

ADR Not regulated.

ADN Not regulated.

15. REGULATORY INFORMATION

US Federal Regulations

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

SARA 311/312 Hazard Categories

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

CWA (Clean Water Act)

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

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355).

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable.

16. OTHER INFORMATION

Revision Date

Revision Note

Not available.

Disclaimer

Sanofi Pasteur considers that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals. Sanofi Pasteur cannot be held liable for any loss, injury or damage from contact with the product.

End of Safety Data Sheet

SAFETY DATA SHEET

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

Product Identifier

Material Name: Metoclopramide Injection (Hospira, Inc.)

Trade Name: Not established
Synonyms: Metoclopramidum
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used for nausea and vomiting (antiemetic)

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

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

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Metoclopramide	364-62-5	206-662-9	Acute Tox 4 (H302)	0.5
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	*
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: If irritation occurs or persists, get medical attention. Rinse thoroughly with plenty of water, also under the eyelids.

Skin Contact: Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.

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: Due to the nature of this material first aid is not normally required.

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 emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

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 product used for nausea and vomiting (antiemetic)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Metoclopramide

Pfizer OEL TWA-8 Hr:	40 µg/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
Hungary OEL - TWA	2 mg/m^3
Japan - OELs - Ceilings	2 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Latvia OEL - TWA	0.5 mg/m^3
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	0.5 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	1 mg/m^3
Switzerland OEL -TWAs	2 mg/m^3

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm 7.5 mg/m^3
Austria OEL - MAKs	5 ppm 8 mg/m^3
Belgium OEL - TWA	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	5 ppm 8.0 mg/m^3
Cyprus OEL - TWA	5 ppm 8 mg/m^3
Czech Republic OEL - TWA	8 mg/m^3
Estonia OEL - TWA	5 ppm 8 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m^3
Germany (DFG) - MAK	2 ppm 3.0 mg/m^3
Greece OEL - TWA	5 ppm 7 mg/m^3
Hungary OEL - TWA	8 mg/m^3
Ireland OEL - TWAs	5 ppm 8 mg/m^3
Italy OEL - TWA	5 ppm 8 mg/m^3
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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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

Exposure Controls

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

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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:	Liquid 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)
Metoclopramide
No data available
Water for injection
No data available
Sodium chloride
No data available
Sodium hydroxide
No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

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

Flammablity:

- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** No data available
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions

- **Oxidizing Properties:** None
- **Conditions to Avoid:** None known
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: Accidental ingestion may cause effects similar to those seen in clinical use.

Known Clinical Effects: Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances. As with all antipsychotic agents, tardive dyskinesia may appear. This syndrome is characterized by rhythmical involuntary movements of the tongue, face, mouth, or jaw. Hypersensitivity reactions may also occur in susceptible individuals.

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

Metoclopramide
Rat Oral LD 50 750 mg/kg
Mouse Oral LD 50 270mg/kg
Rat Intraperitoneal LD 50 114mg/kg

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

Sodium hydroxide

11. TOXICOLOGICAL INFORMATION

Mouse IP LD50 40 mg/kg

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

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

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

Metoclopramide
Embryo / Fetal Development Rat Oral 10 mg/kg/day NOEL Not teratogenic
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOEL Not Teratogenic
Embryo / Fetal Development Mouse Oral 10 mg/kg/day NOEL Not Teratogenic
Embryo / Fetal Development Rabbit Intravenous 10 mg/kg NOEL Not Teratogenic

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

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

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

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been 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

Metoclopramide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3 Schedule 4
EU EINECS/ELINCS List	206-662-9

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

Sodium hydroxide

CERCLA/SARA 313 Emission reporting	Not Listed

15. REGULATORY INFORMATION

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; 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.
Revision date:	04-Jan-2017 Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

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

End of Safety Data Sheet

MATERIAL SAFETY DATA SHEET

1. Product And Company Identification

Product Name: **MetriMist™**

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

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

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

Chemical Emergency Phone Number (Chemical Spills, Leaks, Fire, Exposure or Accident only):
CHEMTREC 1-800-424-9300 (in the US) 1-703-527-3887 (Outside the US)
In Canada Canutec: 1 (613) 996-6666 (24 hours)

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

2. Composition Information

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

3. Hazard Identification

WHMIS: Not controlled under WHMIS.

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

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

Potential chronic health effects with Chronic Misuse of Product:

Chronic health effects: No known significant effects or critical hazards.
Target organs: No known significant effects or critical hazards.
Carcinogenicity Classification: No known significant effects or critical hazards.
Mutagenicity: No known significant effects or critical hazards.
Teratogenicity: No known significant effects or critical hazards.
Developmental effects: No known significant effects or critical hazards.
Fertility effects: No known significant effects or critical hazards.

4. Emergency First Aid Procedures

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

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

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

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

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

5. Fire Fighting Measures

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

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

Hazardous thermal decomposition products: No specific data.

Special Fire Fighting Procedures: None.

6: Accidental Release Measures

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

Environmental precautions:
Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods for cleaning up significant spills:

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

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

7. Handling and Storage

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

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

Other Precautions: Keep out of reach of children.

8. Exposure Controls / Personal Protection

Occupational exposure limits: No exposure limit value known.

Engineering measures: General ventilation is adequate.

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

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

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

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

9. Physical and Chemical Properties

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

10. Stability and Reactivity Data

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

11. Toxicological Information

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

12. Ecological Information

Ecotoxicity: No known significant effects or critical hazards.

13. Disposal Considerations

Waste Disposal: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

14. Transport Information

TDG/IMDG/IATA: Not regulated.

15. Regulatory Information

NONE

16. Other Information

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

HealthLink® A Family of Medical Products
Joining Forces to Serve the Healthcare Community
CLOROX HEALTHCARE®

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 SO_2.

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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.

Nitrogen, refrigerated liquid

Safety Data Sheet P-4630

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

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

SECTION: 1. Product and company identification

1.1. Product identifier

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

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

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

1.3. Details of the supplier of the safety data sheet

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

1.4. Emergency telephone number

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

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

GHS-US classification

Refrigerated liquefied gas H281

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :

GHS04

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

2.3. Other hazards

Other hazards not contributing to the	:	Asphyxiant in high concentrations

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

2.4. Unknown acute toxicity (GHS US)

No data available

SECTION 3: Composition/Information on ingredients

3.1. Substance

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

3.2. Mixture

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

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

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

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

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

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

No additional information available

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

None.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for firefighters

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

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

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

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

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Try to stop release.

6.3. Methods and material for containment and cleaning up

No additional information available

6.4. Reference to other sections

See also sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

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

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

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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

8.2. Exposure controls

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

Hand protection : Wear working gloves when handling gas containers.

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

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

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

Environmental exposure controls : None necessary.

Other information : Wear safety shoes while handling containers.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Gas

Appearance : Colorless liquid.

Molecular mass : 28 g/mol

Color : Colorless liquid.

Odor : No odor warning properties.

Odor threshold : No data available

pH : Not applicable.

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

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

Melting point : -210 °C

Freezing point : No data available

Boiling point : -195.8 °C

Flash point : No data available

Critical temperature : -149.9 °C

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

9.2. Other information

Gas group	:	Refrigerated liquefied gas
Additional information	:	Gas/vapor heavier than air. May accumulate in confined spaces, particularly at or below ground level

SECTION 10: Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None.

10.4. Conditions to avoid

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

10.5. Incompatible materials

None.

10.6. Hazardous decomposition products

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

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

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

SECTION 12: Ecological information

12.1. Toxicity

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

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

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

12.4. Mobility in soil

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

12.5. Other adverse effects

Other adverse effects	:	Can cause frost damage to vegetation.
Effect on ozone layer	:	None
Effect on the global warming	:	No known effects from this product

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

SECTION 14: Transport information

In accordance with DOT

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

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

Additional information

Emergency Response Guide (ERG) Number	:	121 (UN1066);120 (UN1977)
Other information	:	No supplementary information available.
Special transport precautions	:	Avoid transport on vehicles where the load space is not separated from the driver's compartment. Ensure vehicle driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency. Before transporting product containers: - Ensure there is adequate ventilation. - Ensure that containers are firmly secured. - Ensure cylinder valve is closed and not leaking. - Ensure valve outlet cap nut or plug (where provided) is correctly fitted. - Ensure valve protection device (where provided) is correctly fitted.

Transport by sea

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

Air transport

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

SECTION 15: Regulatory information

15.1. US Federal regulations

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

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

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

15.2. International regulations

CANADA

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

EU-Regulations

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

15.2.2. National regulations

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

15.3. US State regulations

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

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

SECTION 16: Other information

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

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

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

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

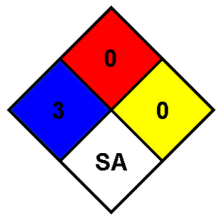
PRAXAIR and the Flowing Airstream design are trademarks or registered trademarks of Praxair Technology, Inc. in the United States and/or other countries.

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

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

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

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



HMIS III Rating

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

Flammability : 0 Minimal Hazard

Physical : 2 Moderate Hazard

SDS US (GHS HazCom 2012) - Praxair

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

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

2.2 : Non-flammable, non-toxic gases

5.1 : Oxidizing substances

Danger

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

1.1. Product identifier

Trade name : Oxygen ; Oxygen Lazer P; Medical Oxygen; Mapcon Oxygen

SDS Nr : YPX097A . (Replaces EIGA097A, 23.02.2010.)

Chemical description : Oxygen
CAS No :7782-44-7
EC No :231-956-9
Index No :008-001-00-8

Registration-No. : Listed in Annex IV / V REACH, exempted from registration.

Chemical formula : O2

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

Relevant identified uses : Industrial and professional. Perform risk assessment prior to use.
Test gas/Calibration gas. Laboratory use.
Shield gas for welding processes. Laser gas.
Plasma gas. Combustion processes. Food applications. Medical applications.
Water treatment.
Use for manufacture of electronic/photovoltaic components.
Contact supplier for more information on uses.

1.3. Details of the supplier of the safety data sheet

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

1.4. Emergency telephone number

Emergency telephone number : 22 59 13 00 [24 t - Giftinformasjonssentralen]
48 00 50 00 [24 t - Beredskapstelefon Yara Praxair]

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

Hazard Class and Category Code Regulation EC 1272/2008 (CLP)

- **Physical hazards** : Oxidizing gases - Category 1 - Danger - (CLP : Ox. Gas 1) - H270
  Gases under pressure - Compressed gas - Warning - (CLP : Press. Gas) - H280

Classification EC 67/548 or EC 1999/45

: O; R8

2.2. Label elements

Labelling Regulation EC 1272/2008 (CLP)

- **Hazard pictograms**

- **Hazard pictograms code** : GHS03 - GHS04
- **Signal word** : Danger
- **Hazard statements** : H270 - May cause or intensify fire; oxidiser.
  H280 - Contains gas under pressure; may explode if heated.
- **Precautionary statements**
  - **Prevention** : P244 - Keep valves and fittings free from oil and grease
    P220 - Keep away from combustible materials.
  - **Response** : P370+P376 - In case of fire : Stop leak if safe to do so.
  - **Storage** : P403 - Store in a well-ventilated place.

2.3. Other hazards

: None.

SECTION 3. Composition/information on ingredients

3.1. Substance / 3.2. Mixture

Substance.

Substance name		Contents	CAS No EC No Index No Registration no	Classification(DSD)	Classification(CLP)
Oxygen	:	100 %	7782-44-7 231-956-9 008-001-00-8 * 1	O; R8	Ox. Gas 1 (H270) Press. Gas Compressed (H280)

Contains no other components or impurities which will influence the classification of the product.
* 1: Listed in Annex IV / V REACH, exempted from registration.
* 2: Registration deadline not expired.
* 3: Registration not required: Substance manufactured or imported < 1t/y.
Full text of R-phrases see section 16. Full text of H-statements see section 16.

SECTION 4. First aid measures

4.1. Description of first aid measures

- **Inhalation** : Remove victim to uncontaminated area.
- **Skin contact** : Adverse effects not expected from this product.
- **Eye contact** : Adverse effects not expected from this product.
- **Ingestion** : Ingestion is not considered a potential route of exposure.

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

: Continuous inhalation of concentrations higher than 75% may cause nausea, dizziness, respiratory difficulty and convulsion.

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

: None.

SECTION 5. Firefighting measures

5.1. Extinguishing media

- **Suitable extinguishing media** : Water spray or fog.
- **Unsuitable extinguishing media** : Do not use water jet to extinguish.

5.2. Special hazards arising from the substance or mixture

Specific hazards : Exposure to fire may cause containers to rupture/explode.
Supports combustion.

Hazardous combustion products : None.

5.3. Advice for fire-fighters

Specific methods : Use fire control measures appropriate for the surrounding fire. Exposure to fire and heat radiation may cause gas receptacles to rupture. Cool endangered receptacles with water spray jet from a protected position. Prevent water used in emergency cases from entering sewers and drainage systems.
If possible, stop flow of product.
Use water spray or fog to knock down fire fumes if possible.

Special protective equipment for fire fighters : Standard protective clothing and equipment (Self Contained Breathing Apparatus) for fire fighters.
Standard EN 137 - Self-contained open-circuit compressed air breathing apparatus with full face mask.
Standard EN 469 - Protective clothing for firefighters. Standard - EN 659: Protective gloves for firefighters.

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

: Try to stop release.
Ensure adequate air ventilation.
Prevent from entering sewers, basements and workpits, or any place where its accumulation can be dangerous.
Monitor concentration of released product.
Eliminate ignition sources.
Evacuate area.

6.2. Environmental precautions

: Try to stop release.

6.3. Methods and material for containment and cleaning up

: Ventilate area.

SECTION 6. Accidental release measures (continued)

6.4. Reference to other sections

: See also sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Safe use of the product : Only experienced and properly instructed persons should handle gases under pressure.
The substance must be handled in accordance with good industrial hygiene and safety procedures.
Use only properly specified equipment which is suitable for this product, its supply pressure and temperature. Contact your gas supplier if in doubt.
Use no oil or grease.
Do not smoke while handling product.
Keep equipment free from oil and grease.
Use only oxygen approved lubricants and oxygen approved sealings.
Use only with equipment cleaned for oxygen service and rated for cylinder pressure.
Ensure the complete gas system was (or is regularily) checked for leaks before use.
Consider pressure relief device(s) in gas installations.

Safe handling of the gas receptacle : Refer to supplier's container handling instructions.
Suck back of water into the container must be prevented.
Open valve slowly to avoid pressure shock.
Do not allow backfeed into the container.
Protect cylinders from physical damage; do not drag, roll, slide or drop.
When moving cylinders, even for short distances, use a cart (trolley, hand truck, etc.) designed to transport cylinders.
Leave valve protection caps in place until the container has been secured against either a wall or bench or placed in a container stand and is ready for use.
If user experiences any difficulty operating cylinder valve discontinue use and contact supplier.
Never attempt to repair or modify container valves or safety relief devices.
Damaged valves should be reported immediately to the supplier.
Keep container valve outlets clean and free from contaminants particularly oil and water.
Replace valve outlet caps or plugs and container caps where supplied as soon as container is disconnected from equipment.
Close container valve after each use and when empty, even if still connected to equipment.
Never attempt to transfer gases from one cylinder/container to another.
Never use direct flame or electrical heating devices to raise the pressure of a container.
Do not remove or deface labels provided by the supplier for the identification of the cylinder contents.

7.2. Conditions for safe storage, including any incompatibilities

: Keep container below 50°C in a well ventilated place.
Segregate from flammable gases and other flammable materials in store. Containers should be stored in the vertical position and properly secured to prevent toppling. Stored containers should be periodically checked for general condition and leakage. Container valve guards or caps should be in place. Store containers in location free from fire risk and away from sources of heat and ignition.
Containers should not be stored in conditions likely to encourage corrosion. Keep away from combustible materials.

7.3. Specific end use(s)

: None.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

DNEL: Derived no effect level (Workers)

: No data available.

PNEC: Predicted no effect concentration

: No data available.

8.2. Exposure controls

8.2.1. Appropriate engineering controls : Systems under pressure shoud be regularily checked for leakages.
Avoid oxygen rich (>23,5%) atmospheres.
Gas detectors should be used when oxidising gases may be released.
Provide adequate general and local exhaust ventilation.
Consider work permit system e.g. for maintenance activities.

8.2.2. Individual protection measures, e.g. personal protective equipment : PPE compliant to the recommended EN/ISO standards should be selected.
A risk assessment should be conducted and documented in each work area to assess the risks related to the use of the product and to select the PPE that matches the relevant risk.
The following recommendations should be considered:
Wear suitable hand, body and head protection. Wear goggles with suitable filter lenses when use is cutting/welding.

• Eye/face protection : Wear safety glasses with side shields.
Standard EN 166 - Personal eye-protection.

• Skin protection

- Hand protection : Wear working gloves when handling gas containers.
Standard EN 388 - Protective gloves against mechanical risk.

- Other : Wear safety shoes while handling containers.
Standard EN ISO 20345 - Personal protective equipment - Safety footwear.
Standard EN ISO 14116 - Limited flame spread materials.
Consider the use of flame resistant safety clothing.

• Respiratory protection : None necessary.

• Thermal hazards : None necessary.

8.2.3. Environmental exposure controls : None necessary.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state at 20°C / 101.3kPa	: Gas.
Colour	: Colourless.
Odour	: No odour warning properties.
Odour threshold	: Odour threshold is subjective and inadequate to warn for overexposure.
pH value	: Not applicable.
Molar mass [g/mol]	: 32
Melting point [°C]	: -219
Boiling point [°C]	: -183
Critical temperature [°C]	: -118
Flash point [°C]	: Not applicable for gases and gas-mixtures.
Evaporation rate (ether=1)	: Not applicable for gases and gas-mixtures.
Flammability range [vol% in air]	: Non flammable.

SECTION 9. Physical and chemical properties (continued)

Vapour pressure [20°C]	: Not applicable.
Relative density, gas (air=1)	: 1.1
Relative density, liquid (water=1)	: 1.1
Solubility in water [mg/l]	: 39
Partition coefficient n-octanol/water [log Kow]	: Not applicable for inorganic gases.
Auto-ignition temperature [°C]	: Not applicable.
Viscosity at 20°C [mPa.s]	: Not applicable.
Explosive Properties	: Not applicable.
Oxidising Properties	: Oxidiser.
- Coefficient of oxygen equivalency (Ci)	: 1

9.2. Other information

Other data : Gas/vapour heavier than air. May accumulate in confined spaces, particularly at or below ground level.

SECTION 10. Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

: Stable under normal conditions.

10.3. Possibility of hazardous reactions

: Violently oxidises organic material.

10.4. Conditions to avoid

: None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

: Consider the potential toxicity hazard due to the presence of chlorinated or fluorinated polymers in high pressure (> 30 bar) oxygen lines in case of combustion.
May react violently with combustible materials.
May react violently with reducing agents.
Keep equipment free from oil and grease.
For additional information on compatibility refer to ISO 11114.

10.6. Hazardous decomposition products

: None.

SECTION 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: No known toxicological effects from this product.
Skin corrosion/irritation	: No known effects from this product.
Serious eye damage/irritation	: No known effects from this product.
Respiratory or skin sensitisation	: No known effects from this product.
Carcinogenicity	: No known effects from this product.
Germ cell mutagenicity	: No known effects from this product.

SECTION 11. Toxicological information (continued)

Reproductive toxicity : No known effects from this product.
STOT-single exposure : No known effects from this product.
STOT-repeated exposure : No known effects from this product.
Aspiration hazard : Not applicable for gases and gas-mixtures.

SECTION 12. Ecological information

12.1. Toxicity

: No ecological damage caused by this product.

12.2. Persistence and degradability

: No ecological damage caused by this product.

12.3. Bioaccumulative potential

: No ecological damage caused by this product.

12.4. Mobility in soil

: No ecological damage caused by this product.

12.5. Results of PBT and vPvB assessment

: Not classified as PBT or vPvB.

12.6. Other adverse effects

Effect on ozone layer : None.
Effect on the global warming : No known effects from this product.

SECTION 13. Disposal considerations

13.1. Waste treatment methods

: May be vented to atmosphere in a well ventilated place.
Do not discharge into any place where its accumulation could be dangerous.
Refer to the EIGA code of practice Doc.30 “Disposal of Gases"", downloadable at http://www.eiga.org for more guidance on suitable disposal methods.

List of hazardous waste codes (from Commision Decision 2001/118/EC) : 16 05 04: Gases in pressure containers (including halons) containing dangerous substances.

13.2. Additional information

: None.

SECTION 14. Transport information

UN number : 1072

Labelling ADR, IMDG, IATA

: 5.1 : Oxidizing substances
2.2 : Non-flammable, non-toxic gases

Land transport (ADR/RID)

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

SECTION 14. Transport information (continued)

H.I. nr	: 25
UN proper shipping name	: OXYGEN, COMPRESSED
Transport hazard class(es)	: 2
Classification code	: 1 O
Packing group	: -
Packing Instruction(s)	: P200
Tunnel Restriction	: E : Passage forbidden through tunnels of category E.
Environmental hazards	: None.

Sea transport (IMDG)

Proper shipping name	: OXYGEN, COMPRESSED
Class	: 2.2
Emergency Schedule (EmS) - Fire	: F-C
Emergency Schedule (EmS) - Spillage	: S-W
Packing instruction	: P200
IMDG-Marine pollutant	: No

Air transport (ICAO-TI / IATA-DGR)

Proper shipping name (IATA)	: OXYGEN, COMPRESSED
Class	: 2.2
Passenger and Cargo Aircraft	: Allowed.
Packing instruction - Passenger and Cargo Aircraft	: 200
Cargo Aircraft only	: Allowed.
Packing instruction - Cargo Aircraft only	: 200

Special precautions for user

: Avoid transport on vehicles where the load space is not separated from the driver's compartment.
Ensure vehicle driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency.
Before transporting product containers:
- Ensure that containers are firmly secured.
- Ensure cylinder valve is closed and not leaking.
- Ensure valve outlet cap nut or plug (where provided) is correctly fitted.
- Ensure valve protection device (where provided) is correctly fitted.
- Ensure there is adequate ventilation.

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

SECTION 15. Regulatory information

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

EU legislation

Restrictions on use	: None.
Seveso directive 96/82/EC	: Listed.

National legislation

National legislation	: Ensure all national/local regulations are observed.

15.2. Chemical safety assessment

SECTION 15. Regulatory information (continued)

: A CSA does not need to be carried out for this product.

SECTION 16. Other information

Indication of changes	: Revised safety data sheet in accordance with commisssion regulation (EU) No 453/2010.
Training advice	: Ensure operators understand the hazard of oxygen enrichment.
List of full text of R-phrases in section 3.	: R8 : Contact with combustible material may cause fire.
List of full text of H-statements in section 3.	: H270 - May cause or intensify fire; oxidiser. H280 - Contains gas under pressure; may explode if heated.
Further information	: This Safety Data Sheet has been established in accordance with the applicable European Union legislation.
DISCLAIMER OF LIABILITY	: Before using this product in any new process or experiment, a thorough material compatibility and safety study should be carried out. Details given in this document are believed to be correct at the time of going to press. Whilst proper care has been taken in the preparation of this document, no liability for injury or damage resulting from its use can be accepted.

End of document

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E-mail: norge@yarapraxair.com

MERCK

Public disclosed

SAFETY DATA SHEET

PRODUCT NAME: PNEUMOVAX™ 23 **Page: 1/6**

Revision 1-Apr-2010

1. Product and Company Identification

Manufactured/Supplied by	Merck Sharp & Dohme Corp. A wholly owned subsidary of Merck & Co., Inc. One Merck Drive Whitehouse Station, NJ 08889-0100 (908) 423-1000 (General Information Only) **Emergency Telephone Number:** 1-908-423-6000 (24/7/365) English Only
Label Name	PNEUMOVAX™ 23
Chemical Name	Pneumococcal vaccine polyvalent
Synonyms	Not available
Material Product Number	4739 - One 5-dose vial of liquid vaccine. 4943 - Single-dose vial of liquid vaccine in a box of 10 single-dose vials. **NDC** 0006-4739-00 **NDC** 0006-4943-00
Intended Use	Vaccine indicated for vaccination against pneumococcal disease caused by those pneumococcal types included in the vaccine.

2. Composition/Information on Ingredients

Component	Molecular Formula	Molecular weight	CAS Number	Percent (%)
Pneumococcal Types 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F	Not available	Not available	Not available	<1
Inactive ingredients	- - -	Not available	- - -	99

EC Label: Not classified.

3. Hazards Identification

Appearance	Clear, colorless solution
Label Text	CAUTION! VACCINE
Emergency Overview	No specific hazard with intact vials. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.
Potential Health Effects	See Section 11 for detailed information.

***** Continued on next page *****

4. First Aid Measures

Eye Contact	None required with normal handling of finished product. In case of contact with eyes, rinse immediately with plenty of water.Get medical attention if symptoms occur.
Skin Contact	None required with normal handling of finished product. Wash with soap and water. Get medical attention if irritation occurs.
Inhalation	None required with normal handling of finished product. If inhaled, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
Ingestion	None required with normal handling of finished product. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.
Notes to physician	Treat supportively and symptomatically. For additional guidance refer to the current prescribing information or the local poison control center.

5. Fire Fighting Measures

Flash Point	Not applicable
Flammable Limits (% in air)	Not applicable
Autoignition Temperature	Not available
Oxidizing Properties	Not available
Combustibility Information	Not available
Dust Explosivity Information	Not applicable
Shock Sensitivity	Not applicable
Fire/Explosion Hazards	None known.
Special Fire Procedures	No special procedures.
Extinguishing Media	In case of fire, use water spray (fog), foam, dry chemical, or CO_2.
Hazardous Decomposition Products	None known.

6. Accidental Release Measures

Personal Precautions	**See Section 8 for Personal Protective Equipment.** Contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures (Section 5).

***** Continued on next page *****

Methods for cleaning up	Contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container 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 container for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. **See Section 13 for Waste Disposal Information**

7. Handling and Storage

Handling	Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.
Storage	Keep container tightly closed. Store vials at 2-8ºC (35.6-46.4ºF)

8. Exposure Controls/Personal Protection

Exposure Guidelines

Component	OSHA Permissible Exposure Limit (PEL)	ACGIH Threshold Limit Value (TLV)	Merck Exposure Control Limit (ECL) or PB-ECL Category
Pneumococcal Types 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F	Not established	Not established	10 ug/m^3 (8-hr TWA)
Inactive ingredients	Not available	Not available	Not established

ADI = 100 ug/day
Wipe Test Criteria = 100 ug/cm^2

Engineering Controls

Adequate ventilation should be provided if there is risk of aerosol formation.

Personal Protective Equipment

Eye/Face Protection	None required when handling sealed vials. Safety glasses with side shields should be worn when handling bulk liquid formulation or filling vials.
Skin Protection	None required when handling sealed vials. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Respiratory Protection	No respiratory protection required when handling bulk liquid formulation or sealed vials. As an adjunct to engineering controls, use an approved, properly fitted, powered air purifying respirator, or respirator of equivalent or greater protection if the potential exists for exposure to airborne aerosols.
Additional Protective Equipment	Work uniform or laboratory coat.

***** Continued on next page *****

9. Physical and Chemical Properties

Appearance	Clear, colorless solution
Odor/Threshold Limit	Not available
pH	Not available
Boiling Point	Not available
Melting Point	Not available
Flash point	Not applicable
Flammable Limits (% in air)	Not applicable
Autoignition Temperature	Not available
Solubility	Not available
Partition Coefficient	Not available
Specific Gravity	Not available
Vapor Density	Not available
Vapor Pressure	Not available
Volatility Component	Not available

10. Stability and Reactivity

Stability	Not available
Conditions to Avoid	Not available
Incompatibility	Not available
Hazardous Polymerization	Not available
Hazardous Decomposition Products	None known.

11. Toxicological Information

Routes of Entry	Ingestion:	No.
	Inhalation:	Yes
	Skin Contact:	No.

Toxicity Data

Component	Test	Species	Route	Result
Pneumococcal Types 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F	Not available	Not available	Not available	Not available
Inactive ingredients	Not available	Not available	Not available	Not available

Effects of Acute Exposure

Eye contact	Non-irritating to the eyes.
Skin contact	Not available
Inhalation	Not available
Ingestion	Not available

*** Continued on next page ***

Effects of Chronic Exposure	Mutagenicity, carcinogenicity, developmental and reproductive toxicity studies have not been conducted with PNEUMOVAX 23. Repeat-dose, developmental, reproductive and genotoxicity studies have not yet been performed. The most common adverse experiences reported in clinical trials were local reactions at the injection site (including soreness, warmth, erythema, swelling, and induration) and fever (<102ºF). In postmarketing experience, injection-site cellulitis-like reactions were reported rarely. Caution and appropriate care should be exercised in administering PNEUMOVAX 23 to individuals with severely compromised cardiovascular and/or pulmonary function in whom a systemic reaction would pose a significant risk.
Carcinogen Designation	Not listed as a carcinogen by OSHA, NTP or IARC.
Medical Conditions Aggravated by Overexposure:	Not available

12. Ecological Information

Environmental Effects	Not available

Ecotoxicity Data

Component	Species	Period	Result
Pneumococcal Types 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F	Not available	Not available	Not available
Inactive ingredients	Not available	Not available	Not available

Environmental Fate	Not available

13. Disposal Considerations

Waste Disposal Information	Avoid contact of spilled material and runoff with soil and surface waterways.Dispose of or treat all spills residues including contaminated soils following all federal, state, or local regulations.

14. Transport Information

Shipping Description

U.S. DOT	Not regulated.
IATA/ICAO	Not regulated.
IMO	Not regulated.
ADR/RID	Not regulated.

***** Continued on next page *****

15. Regulatory Information

U.S. Federal Regulations	Hazardous per OSHA Hazard Communication Standard criteria (29 CFR 1910.1200).
State Regulations	Not available
International Regulations	Not classified as Dangerous according to the Dangerous Substances Directive (DSD).

16. Other Information

Revisions: Material Product Number

Revision:	4/1/2010.
Date of Preparation	10-Apr-2007
Date of Previous Issue	10-Apr-2007
Validation Date	4/1/2010.
MSDS Coordinator:	1-908-423-7903 Merck Sharp & Dohme Corp. A wholly owned subsidary of Merck & Co., Inc. One Merck Drive Whitehouse Station, NJ 08889-0100

Disclaimer:

While this information and recommendations set forth are believed to be accurate as of the date hereof, MERCK & CO, INC. makes no warranty with respect hereto and disclaims all liability from reliance thereon.

SAFETY DATA SHEET

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

Product Identifier

Material Name: Prevnar 13

Trade Name: Prevnar 13; PREVENAR; PREVENAR 13
Synonyms: Pneumococcal 13-Valent Conjugate Vaccine
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

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

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

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.

Additional Information: Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. This substance is not classified as dangerous according to Directive 67/548/EEC.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Pneumococcal 13-valent Conjugate	Not Assigned	Not Listed	Not Listed	*
Aluminum phosphate	7784-30-7	232-056-9	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*
Saline suspension	MIXTURE	Not Listed	Not Listed	*
Succinate buffer	Not assigned	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.

4. FIRST AID MEASURES

Description of First Aid Measures

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

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

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:	Contain the source of 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. Cleanup 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 in a refrigerator.
Storage Temperature:	2 - 8 °C (35 to 45°F)
Specific end use(s):	Vaccine

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Aluminum phosphate

Russia OEL - TWA	6 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.
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:	Homogenous 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)
Saline suspension
No data available
Pneumococcal 13-valent Conjugate
No data available
Aluminum phosphate
No data available
Succinate buffer
No data available
Polysorbate 80
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** No data available
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
- **Oxidizing Properties:** No data available
- **Conditions to Avoid:** Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.

11. TOXICOLOGICAL INFORMATION

Short Term: In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: swelling, tenderness, .? fever, lack of appetite, irritability, sleepiness (somnolence), sleeplessness, allergic reaction, anaphylactic reactions, headache, nausea, diarrhea, and vomiting.

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

Pneumococcal 13-valent Conjugate
Rat Subcutaneous Maximum Non-Lethal Dose .5 mL
Non-human Primate Subcutaneous Maximum Non-Lethal Dose .5mL

Aluminum phosphate
Mouse Oral LD 50 > 5000 mg/kg
Rat Oral LD 50 > 2000mg/kg
Rabbit Dermal LD 50 > 4640 mg/kg

Polysorbate 80
Rat Oral LD50 25 g/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.

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

Pneumococcal 13-valent Conjugate
8 Week(s) Rat Subcutaneous * 0.5 mL NOAEL None identified
13 Week(s) Rat Subcutaneous * 0.5 mL NOAEL None identified
13 Week(s) Monkey Subcutaneous * 0.5 mL NOAEL None identified
Repeated Dose Toxicity Comments: **Pneumococcal 13-valent Conjugate:** * Notes: Doses are administrated 1 Dose/2 Weeks.

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Pneumococcal 13-valent Conjugate
Fertility and Embryonic Development Rabbit Intramuscular 20 times human dose NOAEL No effects at maximum dose, Not teratogenic

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

12. ECOLOGICAL INFORMATION

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

Toxicity: 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

Additonal Information: This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

Ingredients:

Pneumococcal 13-valent Conjugate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Aluminum phosphate

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	232-056-9

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

15. REGULATORY INFORMATION

EU EINECS/ELINCS List	Not Listed

Saline suspension

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Succinate buffer

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

16. OTHER INFORMATION

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information.
Reasons for Revision:	Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.
Revision date:	20-Feb-2018
	Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

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

End of Safety Data Sheet

Conforms to HazCom 2012/United States

SAFETY DATA SHEET

Promethazine HCl Injection, USP

Section 1. Identification

GHS product identifier : Promethazine HCl Injection, USP

Synonyms : Phenergan® (Promethazine HCl) Injection

Product code : Not available.

Chemical family : Anticholinergic Agent. Antihistaminic Agent. Antiemetic. Sedative.

Product type : Regulated prescription drug.

Container information : 1 mL vials or ampuls.

Identified uses : Pharmaceutical.

Supplier's details : Hikma Pharmaceuticals USA Inc.
246 Industrial Way West
Eatontown, New Jersey (NJ) 07724

Emergency telephone number (with hours of operation) : CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887
24/7

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture : SKIN SENSITIZATION - Category 1
AQUATIC HAZARD (LONG-TERM) - Category 3

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : May cause an allergic skin reaction.
Harmful to aquatic life with long lasting effects.

Precautionary statements

General : Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.

Prevention : Wear protective gloves. Avoid release to the environment. Avoid breathing vapor. Contaminated work clothing should not be allowed out of the workplace.

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

Storage : Not applicable.

Section 2. Hazards identification

Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Other means of identification : Phenergan® (Promethazine HCl) Injection

CAS number/other identifiers

CAS number : Not applicable.

Product code : Not available.

Ingredient name	%	CAS number
Water	60 - 100	7732-18-5
Promethazine hydrochloride	1 - 5	58-33-3
Phenol	0.1 - 1	108-95-2
Disodium dihydrogen ethylenediaminetetraacetate	0 - 0.1	139-33-3
Sodium metabisulphite	0 - 0.1	7681-57-4
Calcium chloride	0 - 0.1	10043-52-4

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

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

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

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Section 4. First aid measures

Ingestion : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Skin contact : May cause an allergic skin reaction.

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : Adverse symptoms may include the following:
irritation
redness

Ingestion : No known significant effects or critical hazards.

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

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

Specific treatments : No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

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

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : This material is harmful to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

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

Section 5. Fire-fighting measures

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

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

Methods and materials for containment and cleaning up

Spill : Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. Avoid release to the environment. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

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

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

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties

Appearance

Physical state : Liquid. [Aqueous solution.]

Color : Colorless.

Odor : Not available.

Odor threshold : Not available.

pH : 4 to 5.5

Melting point : Not available.

Boiling point : Not available.

Flash point : Not available.

Evaporation rate : Not available.

Section 9. Physical and chemical properties

Flammability (solid, gas) : Not available.

Lower and upper explosive (flammable) limits : Not available.

Vapor pressure : Not available.

Vapor density : Not available.

Relative density : Not available.

Solubility : Not available.

Partition coefficient: n-octanol/water : Not available.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : Not available.

Section 10. Stability and reactivity

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

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials, acids and alkalis.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

There is no data available.

Irritation/Corrosion

There is no data available.

Sensitization

There is no data available.

Carcinogenicity

There is no data available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Promethazine hydrochloride	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Section 11. Toxicological information

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

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Skin contact : May cause an allergic skin reaction.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : Adverse symptoms may include the following:
irritation
redness

Ingestion : No known significant effects or critical hazards.

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

Short term exposure

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

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

Long term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	13333.3 mg/kg
Inhalation (vapors)	293.3 mg/L

Section 12. Ecological information

Toxicity

There is no data available.

Persistence and degradability

There is no data available.

Bioaccumulative potential

There is no data available.

Mobility in soil

Soil/water partition coefficient (K_{OC}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

AERG : Not applicable.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 14. Transport information

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) PAIR**: Sodium Metabisulphite

TSCA 8(a) CDR Exempt/Partial exemption: Not determined

United States inventory (TSCA 8b): All components are listed or exempted.

Clean Water Act (CWA) 307: Phenol

Clean Water Act (CWA) 311: Phenol

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
Phenol	0.1 - 1	Yes.	-	-	-	-

SARA 304 RQ : Not applicable.

SARA 311/312

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Promethazine hydrochloride	1 - 5	No.	No.	No.	Yes.	No.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

No products were found.

International regulations

Section 15. Regulatory information

International lists : **Australia inventory (AICS)**: All components are listed or exempted.
China inventory (IECSC): Not determined.
Japan inventory: All components are listed or exempted.
Korea inventory: All components are listed or exempted.
Malaysia Inventory (EHS Register): Not determined.
New Zealand Inventory of Chemicals (NZIoC): All components are listed or exempted.
Philippines inventory (PICCS): Not determined.
Taiwan inventory (CSNN): Not determined.

Chemical Weapons Convention List Schedule I Chemicals : Not listed

Chemical Weapons Convention List Schedule II Chemicals : Not listed

Chemical Weapons Convention List Schedule III Chemicals : Not listed

Section 16. Other information

History

Revision date mm/dd/yyyy : 12/15/2018

Version : 2

Prepared by : KMK Regulatory Services Inc.

Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
UN = United Nations

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.
Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

McKESSON

SDS DATE: 11/20/15

SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Select® PVP Prep Solution
MFR #: 035 and 036

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: Select® PVP Prep Solution

SECTION 2: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: Inhalation, Skin

POTENTIAL HEALTH EFFECTS:

EYES: N/A

SKIN: N/A

INGESTION: N/A

INHALATION: N/A

ACUTE HEALTH HAZARDS: N/A

CHRONIC HEALTH HAZARDS: Prolonged and repeated contact may cause skin irritation.

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

SECTION 3 NOTES: N/A

SECTION 4: FIRST-AID MEASURES

EYES: In case of contact, flush with water.

SKIN: In case of contact, flush with water.

INGESTION: N/A

INHALATION: If inhaled move to fresh air.

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 form or foam followed by water.

SPECIAL FIRE FIGHTING PROCEDURES: None.

UNUSUAL FIRE AND EXPLOSION HAZARDS: None.

HAZARDOUS DECOMPOSITION PRODUCTS: None.

SECTION 5 NOTES: N/A

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: Flush with water and clean it thoroughly.

SECTION 6 NOTES: N/A

SECTION 7: HANDLING AND STORAGE

HANDLING: N/A

STORAGE: Store in a cool place.

OTHER PRECAUTIONS: N/A

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

VENTILATION: Good

RESPIRATORY PROTECTION: None

EYE PROTECTION: Goggles should be used.

SKIN PROTECTION: Gloves to minimize skin contact.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: None in ordinary use.

WORK HYGIENIC PRACTICES: N/A

EXPOSURE GUIDELINES: N/A

SECTION 8 NOTES: N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR:

PHYSICAL STATE: Redish brown with characteristic iodine odor, free of particulate matter in suspension, or foreign matter.

pH AS SUPPLIED:
pH (Other): N/A
BOILING POINT: about 105°C/1atm
MELTING POINT: N/A
FREEZING POINT: N/A
VAPOR PRESSURE (mmHg): negligible
@ N/A
DENSITY (lb/gal): 1.6
@ N/A
SPECIFIC GRAVITY (H2O = 1): 1.034
@ N/A
EVAPORATION RATE: N/A

BASIS (=1): N/A

SOLUBILITY IN WATER:

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:	X	

CONDITIONS TO AVOID (STABILITY): None observed and none in ordinary use.

INCOMPATIBILITY (MATERIAL TO AVOID): Strong oxidizing or reducing agents, metal.

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: None.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID (POLYMERIZATION): N/A

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:
Toxicity Test:
Acute oral LD50 (mg/kg): 8,800 (rat)
Sensitization: 5,900 patients over 3 year-0.03% incidence of sensitization (humans)
Skin irritation: Non-irritating to rabbit skin (10% acqueous solution); mildly irritating to rabbit skin (as sold)
Eye irritation: Non-irritating to rabbit eye (10% acqueous solution)

SECTION 11 NOTES: N/A

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:
Biodegradability: Not determined
Aquatic Toxicity: No data available on the adverse effects of this material on the environment.

SECTION 12 NOTES: N/A

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dilute it with lots of water and flush down sewer, non-taxis to regulation for pollution.

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: Comply with all federal, state and local regulations.

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION
PROPER SHIPPING NAME: Not regulated
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

SDS DATE: 11/20/15

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.

FRESENIUS KABI

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Sensorcaine/Sensorcaine-MPF with Epinephrine**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	January 08, 2009
SDS Revision Date:	June 01, 2015
(M)SDS Format:	

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. Category 1.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

Eye: Contact with eyes may cause irritation.

Signs/Symptoms: Possible adverse reactions include: tingling/numbness in exposed areas (parethesia), mild skin irritation, excessive watering of the eye (lacrimation), and may produce numbness of the tongue and anesthetic effects on the stomach. Long term chronic effects are unlikely. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Individuals with a known hypersensitivity to bupivacaine or to any local anesthetic agent of the amide type or to other components of bupivacaine solution.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Bupivacaine Hydrochloride	14252-80-3	- %	
Epinephrine Bitartrate	51-42-3	- %	
Methylparaben	99-76-3	- %	
Sodium Chloride	7647-14-5	- %	
Citric Acid, Anhydrous	77-92-9	- %	

Sodium Metabisulfite	7681-57-4	- %

Note: Sensorcaine®-MPF with Epinephrine does not contain methylparaben.

SECTION 4 : FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes.
Get medical attention if irritation develops or persists.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Other First Aid: For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point: Not established.

Flash Point Method: Not established.

Auto Ignition Temperature: Not established.

Lower Flammable/Explosive Limit: Not established.

Upper Flammable/Explosive Limit: Not established.

Fire Fighting Instructions: Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

Extinguishing Media: Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Protective Equipment: As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

Hazardous Combustion Byproducts: Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel Precautions: Evacuate area and keep unnecessary and unprotected personnel from entering the spill area.
Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.

Environmental Precautions: Avoid runoff into storm sewers, ditches, and waterways.

Methods for containment: Contain spills with an inert absorbent material such as soil, sand or oil dry.

Methods for cleanup: Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.

Storage: Store at controlled room temperature 20 to 25°C (68 to 77°F). Protect from light.

Work Practices: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Hygiene Practices: Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls: General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

Eye/Face Protection: Chemical splash goggles. Wear a face shield also when splash hazard exist.

Skin Protection Description: Protective laboratory coat, apron, or disposable garment recommended.

Hand Protection Description: Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data.

	Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Colorless.
Odor:	Odorless.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Freely soluble
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	3.3-5.5
Molecular Formula:	Mixture
Molecular Weight:	Not established.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Epinephrine is unstable in alkaline solutions when exposed to air or light.

SECTION 11 : TOXICOLOGICAL INFORMATION

Teratogenicity:	Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women of the effect on bupivacaine on the developing fetus.
Bupivacaine Hydrochloride :	
Ingestion:	LD50 Oral Rabbit: 18 mg/kg
Epinephrine Bitartrate :	
RTECS Number:	DO3500000
Ingestion:	Oral - Mouse LD50: 4 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Rat LD50: 82 ug/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 1780 ug/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat TDLo: 0.00001 mg/kg [Cardiac - change in rate Vascular - BP lowering not characterized in autonomic section] Intravenous. - Rat TDLo: 0.001 mg/kg [Cardiac - change in rate Vascular - BP elevation not characterized in autonomic section] Subcutaneous - Rat LD50: 8300 ug/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50: 11100 ug/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat TDLo: 76 mg/kg/42D (intermittent) [Cardiac - other changes Liver - other changes Biochemical - Metabolism (Intermediary) - lipids including transport] Subcutaneous - Mouse TDLo: 2400 ug/kg [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count)] Intraperitoneal. - Mouse LD50: 7800 ug/kg [Cardiac - cardiomyopathy including infarction]
Methylparaben :	
RTECS Number:	DH2450000
Skin:	Administration onto the skin - Rabbit Standard Draize test.: 0.1 mL/24H Administration onto the skin - Rabbit Standard Draize test.: 0.5 mL/21D (Intermittent) Administration onto the skin - Rat TDLo: 374.92 gm/kg/13W (Intermittent) [Nutritional and Gross Metabolic - Weight loss or decreased weight gain Blood - Other changes]
Ingestion:	Oral - Mouse LD50: >8 gm/kg [Peripheral Nerve and Sensation - Flaccid paralysis without anesthesia

(usually neuromuscular blockage) Behavioral - Ataxia]
Oral - Mouse LD50: >8000 mg/kg [Behavioral - Ataxia]
Oral - Rat LD50: 2100 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Mouse TDLo: 100 mg/kg [Vascular - shock Lungs, Thorax, or Respiration - respiratory depression]
Intravenous. - Mouse TDLo: 2.5 mg/kg [Lungs, Thorax, or Respiration - tumors]
Subcutaneous - Mouse TDLo: 165 mg/kg [Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression]
Subcutaneous - Mouse LD50: 1.2 gm/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rat LD50: >500 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse TDLo: 49.5 mg/kg/3D (intermittent) [Related to Chronic Data - changes in uterine weight]
Subcutaneous - Mouse TDLo: 165 mg/kg/3D (intermittent) [Reproductive - Maternal Effects - uterus, cervix, vagina Related to Chronic Data - changes in uterine weight]
Intraperitoneal. - Mouse LD50: 960 mg/kg [Peripheral Nerve and Sensation - flaccid paralysis without anesthesia (usually neuromuscular blockage) Behavioral - somnolence (general depressed activity) Behavioral - ataxia]
Intraperitoneal. - Mouse LD50: 125 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD50: 960 mg/kg [Details of toxic effects not reported other than lethal dose value]

Sodium Chloride :

RTECS Number: VZ4725000

Eye: Eye - Rabbit Standard Draize test.: 10 mg [Moderate]

Skin: Administration onto the skin - Rabbit LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value]
Administration onto the skin - Rabbit Standard Draize test.: 50 mg/24H [mild]
Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]

Inhalation: Inhalation - Rat LC50: >42 gm/m3/1H [Details of toxic effects not reported other than lethal dose value]

Ingestion: Oral - Mouse LD50: 4 gm/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Rat LD50: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rabbit LDLo: 1100 mg/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - muscle contraction or spasticity Cardiac - other changes]
Intravenous. - Guinea pig LDLo: 300 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Mouse TDLo: 2.1 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)]
Intravenous. - Rabbit LDLo: 1.5 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)]
Subcutaneous - Rat LDLo: 3500 mg/kg [Behavioral - irritability]
Subcutaneous - Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Guinea pig LDLo: 2160 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Skin and Appendages - dermatitis, irritative (after systemic exposure)]
Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death]
Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Subcutaneous - Mouse TDLo: 2500 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Subcutaneous - Mouse TDLo: 13440 mg/kg [Reproductive - Fertility - abortion]
Intraperitoneal. - Mouse LD50: 2602 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD50: 2600 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LDLo: 3.72 gm/kg [Behavioral - tremor Behavioral - convulsions or effect on seizure threshold]
Intraperitoneal. - Rat TDLo: 1710 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat TDLo: 10 gm/kg [Reproductive - Effects on Newborn - behavioral]
Intraperitoneal. - Rat Cytogenetic analysis: 2338 mg/kg

Citric Acid, Anhydrous :

RTECS Number: GE7350000

Eye: Eye - Rabbit Standard Draize test.: 750 ug/24H [severe]

Skin: Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]

Ingestion: Oral - Rat LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 5040 mg/kg [Lungs, Thorax, or Respiration - Other changes Musculoskeletal - Other changes]
Oral - Mouse LD50: 7280 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Mouse LD50: 42 mg/kg [Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - cyanosis Gastrointestinal - changes in structure or function of salivary glands]
Intravenous. - Rabbit LD50: 330 mg/kg [Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - cyanosis Gastrointestinal - changes in structure or function of salivary glands]
Subcutaneous - Rat LD50: 5500 mg/kg [Lungs, Thorax, or Respiration - other changes Musculoskeletal - other changes]
Subcutaneous - Mouse LD50: 2700 mg/kg [Lungs, Thorax, or Respiration - other changes Musculoskeletal - other changes]
Intraperitoneal. - Rat LD50: 290 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 903 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD16: 197 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD: 382 mg/kg [Details of toxic effects not reported other than lethal dose value]

Sodium Metabisulfite :

RTECS Number: UX8225000

Eye:	Rabbit, Irritating.
Skin:	Dermal - Rat LD50 : > 2000 mg/kg (TS : Sodium sulfite) (ECHA) Rabbit, Not irritating.
Inhalation:	Inhalation - Rat LC50 : > 5.5 mg/L/4 h (dust/aerosol) (TS : Sodium sulfite) (ECHA)
Ingestion:	Oral - Rat LD50: 1540 mg/kg (OECD SIDS)
Other Toxicological Information:	Intravenous. - Rat LD50: 115 mg/kg Intravenous. - Rabbit LDLo: 192 mg/kg (RTEC)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

Sodium Metabisulfite :

Ecotoxicity:	Japanese rice fish (Oryzias latipes) LC50 (96 hr) >100 mg/L (OECD TG 203) Water flea (Daphnia magna) EC50 (48 hr) = 88.76 mg/L, NOEC (21d) > 10 mg/L (OECD TG 211) Green algae (Scenedesmus subspicatus) OECD TG 201 EC50 (72 hr) =48.1mg/L (OECD SIDS)

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Epinephrine Bitartrate :

EINECS Number:	200-097-1
Canada DSL:	Listed

Methylparaben :

TSCA Inventory Status:	Listed
EINECS Number:	202-785-7
Canada DSL:	Listed

Sodium Chloride :

TSCA Inventory Status:	Listed
EINECS Number:	231-598-3
Canada DSL:	Listed

Citric Acid, Anhydrous :

TSCA Inventory Status:	Listed
EINECS Number:	201-069-1
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.409(80)

Sodium Metabisulfite :

TSCA Inventory Status:	Listed
EINECS Number:	231-673-0
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.1447(1083)

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

SDS Creation Date:	January 08, 2009
SDS Revision Date:	June 01, 2015
SDS Format:	
Disclaimer:	The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or

reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

Sklar

SAFETY DATA SHEET
Sklar Lube Spray

SECTION 1 – PRODUCT IDENTIFICATION

Product Name: **Sklar Lube Spray**
Supplier: Sklar Instruments
Physical Address: 889 South Matlack Street, West Chester, PA, USA, 19382
Tel: 610.430.3200
Fax (USA): 610.696.9007
Fax (International): 610.430.3941
Email (USA): surgi@sklarcorp.com
Email (International): international@sklarcorp.com
Product Description: Ready-to-use Polymeric Lubricant

Ratings	NPFA	HMIS
Health	1	1
Fire	0	0
Reactivity	0	0

SECTION 2 – HAZARD(S) IDENTIFICATION

Main Hazard: No hazardous components as defined by OSHA Hazard Communication Standard 29 CRF 1910.1200.
Primary Route of Entry: Skin and eyes.
Reproduction Hazard: Not Applicable
Potential Health Effects: Signs and Symptoms of Exposure:
Eyes: Slightly irritating but does not irritate eye tissue.
Skin: No hazards expected.
Ingestion: No known effects.
Inhalation: No known effects.

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Name	CAS#	OSHA PEL	ACGIH TLV	% by wt	Other Limits
No Hazardous Components					

SECTION 4 – FIRST AID PROCEDURES

Eyes: Following eye contact, flush eyes immediately with plenty of water, for fifteen minutes. Assure adequate flushing of the eyes by separating the eyelids with fingers. Get medical attention if irritation occurs.
Skin: First aid is normally not required. However, remove grossly contaminated clothing, including shoes, and launder before use.
Ingestion: First aid is normally not required. Not expected to cause serious harm.
Inhalation: Move victim to fresh air if irritation occurs. Get medical attention.

SECTION 5 – FIRE FIGHTING MEASURES

Fire Fighting Procedures: Use self contained breathing apparatus.
Extinguishing Media: Use water spray, carbon dioxide, dry chemical powder or appropriate foam.
Hazardous Combustion Products: None known.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Environmental Precautions: Steps to be taken in the event of spills, leaks or release:
Small Spills: Add inert absorbent, sweep up, and place the material in plastic drums approved for disposal.
Large Spills: Dike to contain and pump into drums approved for disposal. Follow all local, state and federal environmental regulations.

SECTION 7 – HANDLING & STORAGE

Suitable Handling Material: Handle with care and avoid unnecessary personal contact. Avoid contact with eyes and prolonged or repeated skin contact. Wash thoroughly after handling.

Storage Precautions: Keep container tightly closed when not in use and during transport. Store at room temperature.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal Protective Equipment:

General: Protect from clothing by wearing coveralls.

Eye and Face Protection: In cases where there is likelihood of eye contact, wear chemical goggles.

Skin Protection: Wear impervious gloves as a standard handling practice.

SECTION 9 – PHYSICAL & CHEMICAL PROPERTIES

Appearance: White, milk-like

Physical State: Liquid

Odor: Slight oleic odor

pH (0.5oz. per gallon): Not Applicable

Boilng Point: 212°F = 100°C

Freezing Point: Not Applicable

Evaporation Rate (Butyl Acetate = 1): Not Applicable

Flash Point: 293°F = 145°C (Pensky-Martens)

Flammability: Not flammable.

Autoflammability: Not Applicable

Explosive Properties: Not Applicable

Vapor Pressure: Not Applicable

Specific Gravity (H_2O = 1): 1.03

Neurotoxicity: Not Applicable

Solubility in Water: Emulsifies in water

SECTION 10 – STABILITY & REACTIVITY

General Stability Considerations: Product is stable.

Conditions to Avoid: Low hazard but liquid can burn upon heating to temperatures at or above the flashpoint.

Incompatible Materials: None known.

Hazardous Decomposition Products: None known.

Hazardous Polymerization: Will not occur.

SECTION 11 – TOXICOLOGICAL INFORMATION

No Data Available

SECTION 12 – ECOLOGICAL INFORMATION

Enviromental Data: No ecological data has been established.

SECTION 13 – DISPOSAL CONSIDERATIONS

Disposal Methods (For used or unused product): Dispose of in accordance with all local, state and federal regulations.

Disposal of Packaging: Recycle or dispose in accordance with all local, state and federal regulations.

SECTION 14 – TRANSPORT INFORMATION

DOT Regulation: This product does not meet the criteria for a D.O.T. hazardous material as defined by 49 CFR parts 171-173.

Proper Shipping Name: Water emulsible lubricant.

SECTION 15 – REGULATORY INFORMATION

None

SECTION 16 – OTHER INFORMATION

None

SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Sodium Chloride Injection (Hospira, Inc.)

Trade Name: Not established
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used for electrolyte replacement

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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	*

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Due to the nature of this material first aid is not normally required.

Skin Contact: Due to the nature of this material first aid is not normally required.

Ingestion: Due to the nature of this material first aid is not normally required.

Inhalation: Not an expected route of exposure.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Not applicable

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

Not applicable

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Not applicable

Environmental Precautions

None

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Wipe up with a damp cloth and place in container for disposal.

Additional Consideration for Large Spills: None

7. HANDLING AND STORAGE

Precautions for Safe Handling

No special handling requirements for normal use of this material.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Incompatible Materials: None
Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

SODIUM CHLORIDE

Latvia OEL - TWA	5 mg/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.

SODIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m^3 to 3000ug/m^3)

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures.
Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Not required for the normal use of this product.
Eyes: Not required under normal conditions of use.
Skin: Not required for the normal use of this product.
Respiratory protection: None required under normal conditions of use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	**Color:**	Colorless
Odor:	None	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
SODIUM CHLORIDE
No data available
Water for injection
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: None
Incompatible Materials: None
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: Mild eye irritant in experimental animals (based on components)

Acute Toxicity: (Species, Route, End Point, Dose)

SODIUM CHLORIDE
Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m^3
Rat Oral LD 50 3g/kg
Mouse Oral LD 50 4g/kg
Rabbit Dermal LD 50 > 10g/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

11. TOXICOLOGICAL INFORMATION

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: No harmful effects to aquatic organisms are expected.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

SODIUM CHLORIDE

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Data Sources: Publicly available toxicity information.

Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 07-Dec-2016

Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Hydrocortisone Sodium Succinate for Injection (Act-O-Vial)

Trade Name: Solu-Cortef
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anti-inflammatory

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2

EU Classification:

EU Indication of danger: Toxic to Reproduction: Category 3

EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.

Label Elements

Signal Word: Warning
Hazard Statements: H361d - Suspected of damaging the unborn child

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards No data available
Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Hydrocortisone Sodium Succinate	125-04-2	204-725-5	Repr.Cat.3;R63	Repr. 2 (H361d)	< 86
Sodium hydroxide	1310-73-2	215-185-5	C; R35	Skin Corr. 1A (H314)	**
Benzyl Alcohol	100-51-6	202-859-9	Xn; R20/22	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	<14

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sodium phosphate, monobasic	7558-80-7	231-449-2	Not Listed	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	Not Listed	*

Additional Information: * Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Carbon dioxide, carbon monoxide

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. Avoid breathing dust. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Hydrocortisone Sodium Succinate

Pfizer OEL TWA-8 Hr:	100µg/m^3, Skin

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m^3
Australia PEAK	2 mg/m^3
Austria OEL - MAKs	2 mg/m^3
Bulgaria OEL - TWA	2.0 mg/m^3
Czech Republic OEL - TWA	1 mg/m^3
Estonia OEL - TWA	1 mg/m^3
France OEL - TWA	2 mg/m^3
Greece OEL - TWA	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Japan - OELs - Ceilings	2 mg/m^3
Latvia OEL - TWA	0.5 mg/m^3
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	0.5 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	1 mg/m^3
Switzerland OEL -TWAs	2 mg/m^3

Benzyl Alcohol

Bulgaria OEL - TWA	5.0 mg/m^3
Czech Republic OEL - TWA	40 mg/m^3
Finland OEL - TWA	10 ppm 45 mg/m^3
Latvia OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	5 mg/m^3
Poland OEL - TWA	240 mg/m^3

Analytical Method: Analytical method available for hydrocortisone. Contact Pfizer Inc for further information.

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder plus sterile diluent	**Color:**	White to off-white
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
Solubility: Soluble: Water
pH: 7-8 (solution)
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Sodium phosphate, dibasic
No data available
Sodium phosphate, monobasic
No data available
Sodium hydroxide
No data available
Hydrocortisone Sodium Succinate
No data available
Benzyl Alcohol
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** No data available
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under recommended storage conditions. Solutions are unstable after 4 hours.
Possibility of Hazardous Reactions
- **Oxidizing Properties:** No data available
- **Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause eye, skin and respiratory tract irritation (based on components) . May be absorbed through the skin in harmful amounts. Central nervous system effects such as headache, dizziness, drowsiness, fatigue, and lack of muscular coordination can also occur. May cause stomach irritation, diarrhea, nausea, or vomiting.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects: Effects on vision have been seen during clinical use. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes. Clinical use may cause an increase in blood pressure (hypertension). Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Acute Toxicity: (Species, Route, End Point, Dose)

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Hydrocortisone Sodium Succinate
Rat Oral LD 50 5000 mg/kg
Mouse Oral LD 50 5000mg/kg
Rat Subcutaneous LD 50 449mg/kg
Mouse Subcutaneous LD 50 >500mg/kg
Rat Intraperitoneal LD 50 150mg/kg

Benzyl Alcohol
Rat Oral LD50 1230 mg/kg
Rat Para-periosteal LD50 53mg/kg

Rat Inhalation LC50 >4.178mg/L

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Hydrocortisone Sodium Succinate
Eye Irritation Rabbit Minimal

Benzyl Alcohol
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate
Skin Irritation Guinea Pig Moderate

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Hydrocortisone Sodium Succinate
7 Day(s) Mouse Oral 140 mg/kg/day LOAEL Thymus
4 Day(s) Mouse Subcutaneous 100 mg/kg/day LOAEL Liver

11. TOXICOLOGICAL INFORMATION

11 Day(s) Mouse Subcutaneous 62 mg/kg/day LOAEL Endocrine system
2 Week(s) Mouse Subcutaneous 560 mg/kg/day LOAEL Liver, Bone Marrow
85 Day(s) Rat Subcutaneous 175 mg/kg/day LOAEL Adrenal gland

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Hydrocortisone Sodium Succinate
Reproductive & Fertility-Females Rat Oral 210 mg/kg/day LOAEL Maternal toxicity
Embryo / Fetal Development Mouse Oral 10 mg/kg/day LOAEL Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Hydrocortisone Sodium Succinate
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo In Vitro Direct DNA Damage Rat , Mouse Positive
In Vivo In Vitro Chromosome Aberration Rat , Mouse Positive
Cytogenetics Mouse Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Hydrocortisone Sodium Succinate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	204-725-5

Sodium hydroxide

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Benzyl Alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

Sodium phosphate, monobasic

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-449-2

Sodium phosphate, dibasic

15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-448-7

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

Toxic to Reproduction: Category 3
C - Corrosive
Xn - Harmful

R35 - Causes severe burns.
R63 - Possible risk of harm to the unborn child.
R20/22 - Harmful by inhalation and if swallowed.

Data Sources:	Safety data sheets for individual ingredients. Pfizer proprietary drug development information. Publicly available toxicity information.
Reasons for Revision:	Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 13 - Disposal Considerations. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.
Revision date:	16-May-2014
	Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Methylprednisolone Sodium Succinate for Injection, USP

Trade Name: Solu-Medrol; Solu-Medrone; Solu-Moderin
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anti-inflammatory

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A
Specific target organ systemic toxicity (repeated exposure): Category 2

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger

Hazard Statements:
H373 - May cause damage to organs through prolonged or repeated exposure H360D - May damage the unborn child
May form combustible dust concentrations in air

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P314 - Get medical attention/advice if you feel unwell
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Benzyl Alcohol	100-51-6	202-859-9	Acute Tox.4 (H302) Acute Tox.4 (H332)	<1.0
Methylprednisolone Sodium Succinate	2375-03-3	219-156-8	Repr. 1A (H360D) STOT RE 2 (H373)	67-87

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium phosphate, monobasic	7558-80-7	231-449-2	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. Avoid breathing dust. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Benzyl Alcohol

Bulgaria OEL - TWA	5.0 mg/m^3
Czech Republic OEL - TWA	40 mg/m^3
Finland OEL - TWA	10 ppm 45 mg/m^3
Latvia OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	5 mg/m^3
Poland OEL - TWA	240 mg/m^3

Methylprednisolone Sodium Succinate

Pfizer OEL TWA-8 Hr:	4 µg/m^3, Skin

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands:	Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection:	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder	**Color:**	White
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility:	Soluble: Alcohols
Water Solubility:	No data available
Solubility:	Soluble: Water
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)
Sodium phosphate, dibasic
No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

Sodium phosphate, monobasic
No data available
Lactose
No data available
Methylprednisolone Sodium Succinate
No data available
Methylprednisolone
Predicted 7.4 Log D 1.99
Benzyl Alcohol
No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** No data available
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
- **Oxidizing Properties:** No data available
- **Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of various forms of the active ingredients. The remaining information describes the potential hazards of the individual ingredients.
Short Term: May cause eye irritation (based on components) . May be harmful if absorbed through the skin.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs.
Known Clinical Effects: Adverse clinical reactions include the development of hypersensitivity and/or irritation leading to rashes, itching, and burning. Clinical use has resulted in hormonal alterations. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes.

Acute Toxicity: (Species, Route, End Point, Dose)

11. TOXICOLOGICAL INFORMATION

Methylprednisolone Sodium Succinate
Rat Oral LD 50 > 5000 mg/kg
Rat Para-periosteal LD 50 718mg/kg
Mouse Intravenous LD 50 953mg/kg
Rat Intraperitoneal LD 50 512mg/kg
Mouse Intraperitoneal LD 50 902mg/kg

Methylprednisolone
Rat Oral LD 50 > 2000 mg/kg
Mouse Oral LD 50 450mg/kg
Rat Intraperitoneal LD 50 1000mg/kg
Mouse Intraperitoneal LD 50 1409mg/kg
Rat Subcutaneous LD 50 >3000mg/kg

Benzyl Alcohol
Rat Oral LD50 1230 mg/kg
Rat Para-periosteal LD50 53mg/kg
Rat Inhalation LC50 >4.178mg/L

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Methylprednisolone
Skin Irritation Rabbit No effect
Eye Irritation Rabbit No effect
Skin Sensitization - GPMT Guinea Pig No effect

Benzyl Alcohol
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Minimal
Skin Irritation Guinea Pig Moderate

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Methylprednisolone
42 Day(s) Dog Oral 167 µg/kg/day LOAEL Adrenal gland
6 Week(s) Rat Subcutaneous 500 µg/kg/day LOAEL None identified
14 Week(s) Rat Subcutaneous 0.4 µg/kg/day NOAEL Blood forming organs, Adrenal gland
52 Week(s) Rat Subcutaneous 4 µg/kg/day NOAEL Blood forming organs Adrenal gland

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Methylprednisolone Sodium Succinate
Reproductive & Fertility Rat Subcutaneous 40 mg/kg/day LOAEL Fetotoxicity
Embryo / Fetal Development Rat Subcutaneous 40 mg/kg/day LOAEL Teratogenic

Methylprednisolone

11. TOXICOLOGICAL INFORMATION

Reproductive & Fertility	Rat	Subcutaneous	0.004	mg/kg/day	NOAEL	Paternal toxicity
Reproductive & Fertility	Rat	Subcutaneous	0.02	mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Subcutaneous	1.0	mg/kg/day	LOAEL	Fetotoxicity, Teratogenic
Embryo / Fetal Development	Mouse	Intramuscular	330	mg/kg/day	LOAEL	Teratogenic
Embryo / Fetal Development	Rabbit	Intramuscular	0.1	mg/kg/day	LOAEL	Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Methylprednisolone Sodium Succinate
Direct DNA Interaction Not applicable Negative
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.

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

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:
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.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Benzyl Alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

Sodium phosphate, monobasic

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-449-2

Sodium phosphate, dibasic

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-448-7

Lactose

15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-559-2

Methylprednisolone Sodium Succinate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	219-156-8

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child

Data Sources:	Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.
Reasons for Revision:	Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.
Revision date:	27-Oct-2016
	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

US - OSHA SAFETY DATA SHEET

Issue Date 5/11/15 **Revision Date** **Version** 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Tylenol Child Oral Suspension

Other means of identification

Product Code C-432, C-476

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Temporarily reduces fever. Temporarily relieves minor aches and pains due to: the common cold, flu, headache, sore throat, and toothaches.

Uses advised against None Known.

Details of the supplier of the safety data sheet

Supplier Address

McNeil Consumer Healthcare, Division of
McNeil-PPC, Inc.
7050 Camp Hill Rd.
Fort Washington, PA
10934-2299

Emergency telephone number

Company Phone Number (215) 273-7000

24 Hour Emergency Phone Number For 24-hour emergency assistance, call the 3E Company at 1 (877)-236-9871
Provide the technician with the following product tracking code: 2277

2. HAZARDS IDENTIFICATION

Classification

Health Hazards

Not classified.

Physical hazards

Not Classified.

OSHA Regulatory Status

This product is safe for consumers when used according to the label directions. Potential hazards that may occur if product is not used according to the consumer label are as follows in this Safety Data Sheet (SDS).

Label elements

Emergency Overview

Hazard statements
This material does not meet the criteria for classification.

Hazard Symbol
None

Signal word
None

Appearance Red, cherry flavored suspension
Purple to reddish purple suspension with a characteristic grape odor

Physical state Liquid

Odor Characteristic grape Cherry

Precautionary Statements - Prevention
Not available.

Precautionary Statements - Response
No specific first aid measures noted.

Precautionary Statements - Storage
Store at 20 -25 °C (68 - 77 °F) in a dry place.

Precautionary Statements - Disposal
Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards not otherwise classified (HNOC)
Not classified.

Other Information

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms None

Chemical Name	CAS No.	Weight-%
High Fructose Corn Syrup	977042-84-4	70-80
Sorbitol Solution 70%	50-70-4	10-30
Glycerin	56-81-5	1-15
Acetaminophen	103-90-2	1-5

4. FIRST AID MEASURES

First aid measures

Eye contact In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin Contact Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing if required, then physically remove as much of the product as possible. Wash affected area with soap and water, then thoroughly flush the area with water. If irritation persists, seek medical advice.

Inhalation If symptomatic, move to fresh air. Get medical attention if symptoms persist.

Ingestion If symptomatic, seek medical advice. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms and effects, both acute and delayed
Symptoms No information available.

Indication of any immediate medical attention and special treatment needed
Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical
Not applicable.

Explosion data
Sensitivity to Mechanical Impact None known.
Sensitivity to Static Discharge None known.

Protective equipment and precautions for firefighters
Wear self-contained breathing apparatus and protective clothing.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
Personal precautions Wear appropriate personal protective equipment (see Section 8).

Environmental precautions
Environmental precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up
Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Vacuum and place into proper container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling
Advice on safe handling Observe good industrial hygiene practices. Minimize dust generation and accumulation.

Conditions for safe storage, including any incompatibilities
Storage Conditions Keep only in the original container. Store between 20 - 25 °C (68 - 77 °F). Keep away from food, drink, and animal feedingstuffs. Keep out of reach of children.

Incompatible materials None known based on information supplied. Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters
Biological limit values No biological limits noted for this ingredient(s).

Exposure Guidelines Based on a review of animal and clinical literature, an Occupational Exposure Limit (OEL) of 3000 µg/m^3 is recommended as an 8-hour TWA for Acetaminophen.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH
Glycerin 56-81-5	-	TWA: 15 mg/m^3 mist, total particulate	-

		TWA: 5 mg/m^3 mist, respirable fraction	

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin and body protection None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, and hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Hand protection Use protective gloves. None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information

Respiratory protection None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

General Hygiene Considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid		
Appearance	Red, cherry flavored suspension Purple to reddish purple suspension with a characteristic grape odor	**Odor**	Characteristic grape Cherry
Color	Red Purple	**Odor threshold**	Not available.

Property	**Values**	**Remarks • Method**
pH	Not available.	
Melting point/freezing point	Not available.	
Boiling point / boiling range	Not available.	
Flash point	Not available.	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	Not available.	
Lower flammability limit:	Not available.	
Vapor pressure	Not available.	

Vapor density	Not available.
Specific Gravity	Not available.
Water solubility	Not available.
Solubility in other solvents	Not available.
Partition coefficient	Not available.
Autoignition temperature	Not available.
Decomposition temperature	Not available.
Kinematic viscosity	Not available.
Dynamic viscosity	Not available.
Explosive properties	Not available.
Lower explosive limit	Not available.
Upper explosive limit	Not available.
Oxidizing properties	Not available.

10. STABILITY AND REACTIVITY

Reactivity
Stable at normal conditions.

Chemical stability
Stable.

Possibility of Hazardous Reactions
Hazardous polymerization does not occur.

Conditions to avoid
Low and elevated temperatures. Minimize dust generation and accumulation.

Incompatible materials
None known based on information supplied. Strong oxidizing agents.

Hazardous Decomposition Products
Carbon oxides. Silicon oxides. Nitrogen oxides. Sodium oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information No data available.

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Eye contact May cause eye irritation on direct contact.

Skin Contact This product is not expected to be a skin hazard.

Ingestion Expected to be a low ingestion hazard.

Acute Effects

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Sorbitol Solution 70% 50-70-4	= 15900 mg/kg (Rat)	-	-	-
Glycerin 56-81-5	= 12600 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 570 mg/m^3 (Rat) 1 h	-
Acetaminophen 103-90-2	= 1944 mg/kg (Rat) = 338 mg/kg (Mouse)	-	-	-

Information on toxicological effects

Symptoms When used as directed, side effects associated to acetaminophen are rare. If ingested in large doses, long-term chronic use or with alcohol, acetaminophen may cause liver damage, acute renal failure and jaundice.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation Not available.
Serious eye damage/eye irritation Not available.
Irritation Not available.
Corrosivity Not available.
Sensitization This product is not expected to cause skin sensitization.
Germ cell mutagenicity There is no evidence to suggest that acetaminophen is mutagenic.
Carcinogenicity There is no evidence to suggest that acetaminophen is carcinogenic.

Chemical Name	ACGIH	IARC	NTP	OSHA
Acetaminophen 103-90-2	-	Group 3	-	-

Reproductive toxicity In rats and mice, high oral doses of acetaminophen impaired spermatogenesis and caused testicular atrophy. At oral doses up to 250 mg/kg/day during gestation, this drug was not teratogenic in mice or rats and did not cause intrauterine growth abnormalities in rats
Developmental Toxicity Not available.
Teratogenicity Not available.
STOT - single exposure Not classified.
STOT - repeated exposure Not classified.
Chronic toxicity Not available.
Subchronic toxicity Not available.
Target Organ Effects Not available.
Neurological effects Not available.
Other adverse effects Not available.
Aspiration hazard Due to the physical form of the product it is not an aspiration hazard.

Numerical measures of toxicity - Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity
This product's components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability
No information available.

Bioaccumulation
No information available.

Mobility
No information available.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods
Disposal of wastes Dispose in accordance with applicable federal, state, and local regulations.

Local disposal regulation	Dispose in accordance with local regulations.
Hazardous waste code	Hazardous waste codes should be determined in accordance with hazardous waste regulatory authorities.
Waste from residue / unused packaging	Dispose in accordance with applicable regulations
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. TRANSPORT INFORMATION

DOT	Not regulated as a hazardous material by DOT.
IATA	Not regulated as a dangerous good.
IMDG	Not regulated as a dangerous good.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	This substance/mixture is not intended to be transported in bulk.

15. REGULATORY INFORMATION

International Inventories

TSCA	Does not comply
DSL/NDSL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

US Federal Regulations

US OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Over-the-counter drugs in their solid final form (e.g. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous listed

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

Drug Enforcement Administration (DEA) List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))
Not regulated

DEA Exempt Chemical Mixtures Code Number
Not regulated

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPS) List
Not regulated

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

Safe Drinking Water Act (SDWA)
Not regulated

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations
This product may contain substances regulated by state right-to-know regulations.

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Glycerin 56-81-5	X	X	X

U.S. EPA Label Information
EPA Pesticide Registration Number Not available.

16. OTHER INFORMATION

Issue Date 5/11/15
Revision Note
Not available.

Disclaimer
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

Varivax® and Zostavax®

SAFETY DATA SHEET

IMPORTANT NOTICE **This Safety Data Sheet (SDS) is prepared by Seqirus Pty. Ltd. in accordance with Safe Work Australia National Code of Practice for the Preparation of Safety Data Sheets (February 2016). The information contained herein must not be altered or deleted. Additional information may be appended to the SDS, but it must be marked clearly to indicate that it is not part of the original.**

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product Name	Varivax®, Zostavax®
Other Names	Attenuated Varicella Virus
Manufacturer's Product Code	Varivax®: 80740501, 80740507, 80740507 Zostavax®: 80760101, 80760107
Use	Vaccination against Varicella infection (chicken pox)
Supplier Name	Seqirus Pty Ltd (ABN 26 160 735 035)
Address	63 Poplar Road, Parkville, Victoria 3052, Australia
Telephone	+61 3 9389 2000
Emergency Telephone	+61 3 9389 1984 (24hr)

2. HAZARDS IDENTIFICATION

Not classified as a hazardous chemical according to Australian WHS Regulations

GHS Classification(s)	None Allocated
Signal Word	No Signal Word
Pictogram(s)	No Pictogram(s)
Hazard Statement(s)	None Allocated
Prevention statement(s)	None Allocated
Response	None Allocated
Storage	None Allocated
Disposal	None Allocated

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name:	*CAS Number:*	*Proportion:*
Oka/Merck varicella virus (weakened strain of varicella virus)	-	1350PFU (Plaque Forming Unit) when constituted with diluents and stored at room temperature for 150 mins per 0.5mL dose
Other non-hazardous ingredients	-	Up to 100%

4. FIRST AID MEASURES

Eye Flush eye thoroughly with water for at least 15 minutes. If irritation occurs, seek immediate medical attention.

Ingestion DO NOT induce vomiting. Wash out mouth thoroughly with water and give plenty of water to drink.

Skin Remove contaminated clothing. Wash affected areas thoroughly with soap and water. Seek medical attention in event of irritation.

Inhaled If inhaled, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

First Aid Facilities Ensure water is available at point of use.

Advice to Doctor Treat symptomatically.

5. FIRE FIGHTING MEASURES

Fire/Explosion Hazard None known

Fire Extinguishing Media
- Water spray
- Carbon dioxide (CO2)
- Powder
- Foam

Hazchem Code None allocated

6. ACCIDENTAL RELEASE MEASURES

Minor Spills
- Contain spilled material
- Use absorbent (or soil, in absence of other suitable material)
- Scoop up material and place in a sealed, liquid-proof container for disposal
- Disinfect the affected area with 70% ethanol or a freshly made 10% bleach solution

Major Spills
- Contain material ensuring runoff does not reach a waterway
- Place spilled material in an appropriate container for disposal
- Minimise contact of spilled material with soil to prevent runoff to surface waterways
- Disinfect the affected area with 70% ethanol or a freshly made 10% bleach solution

7. HANDLING AND STORAGE

- Avoid contact with skin and eyes.
- Keep it where children cannot reach it.
- Store at 2 to 8 degrees Celsius.
- Do not freeze vaccine.
- Protect the injection from light be it keeping it in the original pack until it is time for it to be given.
- Do not use after the expiry date on the label.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards No exposure limits set by SWA or ACGIH.

Engineering Controls Adequate ventilation should be provided if there is a risk of aerosol formation. None required when handling sealed vials.

Personal Protection None is required when handling sealed vials. Safety glasses and protective gloves should be worn when handling bulk liquid formulation or filling vials. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	White powder
Odour	Not determined
pH	Not determined
Boiling Point/Melting Point	Not determined
Vapour Pressure	Not determined
Vapour Density	Not determined
Specific Gravity	Not determined
Flashpoint	Not determined
Flammability Limits	Not determined
Solubility in Water	Not determined

10. STABILITY AND REACTIVTY

Reactivity Not available

Stability Not available

Decomposition Products None known

11. TOXICOLOGICAL INFORMATION

Eye Formulation may be irritating.

Ingestion Not available

Skin May cause mild irritation.

Inhaled Not an expected route of exposure.

Chronic Health Effects No chronic health effects expected under conditions of use

Special Circumstances **Immune status:** Changes in the immune system due to cancer or cancer therapy (radiation or chemotherapy), steroid use, tuberculosis, organ transplant or diseases of the immune system (including HIV/AIDS) must be reported immediately to their occupational health group or personal physician, as appropriate. The US Advisory Committee on Immunizations Practices (ACIP) has recommended severely immune compromised individuals not be exposed to live virus vaccines, as there is a risk of severe complications.

Pregnancy: Women who are considering pregnancy should consult with their occupational health group or physician prior to conception. Since the wildtype virus can damage the developing fetus (congenital varicella syndrome), a registry has been established by Merck and the Centers for Disease Control and Prevention (CDC) to follow pregnant women inadvertently inoculated with the varicella vaccine or who became pregnant within 3 months of being vaccinated. Fetuses of women with known immunity are not considered to be at risk for congenital varicella syndrome.

12. ECOLOGICAL INFORMATION

- No data available.
- For good environmental practice avoid discharge to waterways.

13. DISPOSAL CONSIDERATIONS

- In accordance with state land and waste management authority.

14. TRANSPORT INFORMATION

Not Classified as a dangerous good by the criteria of the ADG Code

UN Number	None allocated
DG Class	None allocated
Subsidiary Risk	None allocated
Packing Group	None allocated
Hazchem Code	None allocated

15. REGULATORY INFORMATION

Poisons Schedule Number Schedule 4 (S4) – Prescription only medicine

16. OTHER INFORMATION

Last Revised 15 November 2016

Reason for Revision
- Update to GHS requirements
- Update Business contact details
- Update Composition and Physical properties information
- Updated NOHSC to SWA

Abbreviations

SWA	- Safe Work Australia
GHS	- Globally Harmonised System
WHS	- Work, Health and Safety
ADG Code	- Australian Dangerous Goods Code
UN Number	- United Nations Number
DG Class	- Dangerous Goods Class
CAS Number	- Chemical Abstract Service Number

Contact Point

Company Contact:	+61 3 9389 1984 (24hr)
Australian Poisons Information Centre, 24 hour service:	13 11 26
Australian Police, Fire Brigade or Ambulance:	000
New Zealand Poisons Information Centre, 24 hour service:	0800 764 766
New Zealand Police, Fire Brigade or Ambulance:	111

Whilst the information contained in this document is based on data which, to the best of our knowledge, was accurate and reliable at the time of preparation, no responsibility can be accepted by us for errors and omissions. Users are advised to make their own determination as to the suitability of this information in relation to their particular purposes and specific circumstances. Since the information contained in this document may be applied under conditions beyond our control, we can accept no responsibility for any loss or damage by any person acting or refraining from action as a result of this information.

MEDICAL CHEMICAL CORPORATION
SINCE 1954

SDS for Wavicide-01
Catalog # 0104-1gl and 0112-32oz

Medical Chemical Corp.
19430 Van Ness Ave.
Torrance, CA 90501
Customer Service: Phone (310)787-6800
FAX (310)787-4464
CHEMTREC Emergency Response Telephone Number: (800)424-9300
Note: The CHEMTREC phone number is only for emergencies involving spills, leaks, fire, exposure or accident. Please direct all other inquiries to our customer service phone number.

Section I - Product Identification

An aqueous, buffered glutaraldehyde solution. Slightly acidic pH (The pH is about the same as the pH of distilled water).

Section II - Hazards Identification

Warning: Causes skin irritation. Wash thoroughly after handling. Wear protective clothing, eye and face protection. If swallowed, rinse mouth and Immediately contact a poison control center. Remove contaminated clothing and wash before reuse. Rinse skin with water. .

Safety Ratings

Health: Slightly Hazardous *Flammability:* None *Reactivity*: None *Contact:* Slight
Recommended safety equipment: safety goggles, lab coat and proper gloves
Storage: General storage
NFPA Ratings
Health = 1 Flammability = 0 Reactivity = 0

Potential Health Effects

The toxicology of this compound have not been completely examined. It is presumed that the toxicity of this item is similar to other aldehydes.
Inhalation: Irritating to respiratory tract. May cause asthma like symptoms in sensitive individuals.
Ingestion: Can cause irritation and chemical burns to the mouth, throat, esophagus and stomach. Can also cause nausea, vomiting, diarrhea, etc.
Skin contact: May cause skin irritation or aggravation of existing dermatitis. May cause temporary discoloration of the skin.
Eye contact: Vapors may cause stinging sensation and tearing. Solution contact can cause corneal injury which can cause visual impairment if not dealt with immediately.
Chronic Exposure: May be a sensitizer in some individuals.
Aggravation of preexisting conditions: May aggravate preexisting asthma and other lung diseases.

Section III - Composition/Information on Components

Ingredients	*CAS#*	*OSHA Pel*	*ACGIH TLV*	*Other Limits*	*%*
Glutaraldehyde	111-30-8	0.2 ppm	0.05 ppm		2.65%

Wavicide-01 also contains proprietary buffers, surfactants and defoamers.

Section IV - First Aid Measures

Inhalation: Remove from source of exposure and get medical attention for any breathing difficulty.
Ingestion: Do not induce vomiting. Drink large quantities of fluids and call a physician immediately.
Note to Physician: Probable mucosal damage from oral exposure may contraindicate gastric lavage.
Skin Contact: Remove contaminated clothing and wash affected area with soap and water. Get medical advice if *irritation develops*. Wash or discard contaminated clothing before reuse.
Eye Contact: Immediately flush thoroughly with running water for at least 15 minutes. Get immediate medical advice.

Section V - Fire Fighting Measures

Flash point: Not applicable.
Flammable Limits: Not applicable.
Fire: Not normally a fire Hazard.
Explosion: Not Normally an explosion hazards.
Fire Extinguishing Media: Any means suitable for surrounding fire.
Special information: Pyrolysis will release carbon monoxide.

Section VI - Accidental Release Measures

Wear appropriate protective gear such as gloves, apron and protective eye wear. Absorb with a suitable absorbent (such as paper towels) and store in a suitable container for disposal. Large spills may be neutralized with sodium bisulfite (about 200 g/gallon), glycine or ammonia.

Section VII - Handling and Storage

Store in a closed container at controlled room temperature, 59 °F to 86 °F (15 °C to 30 °C). Solution that is being reused should be stored in a tightly closed container and used in a room with adequate ventilation (i.e. at least ten changes of air per hour).

Section VIII - Exposure Control/Personal Protection

Airborne Exposure Limits: See section III.
Ventilation System: Use appropriate ventilation. ANSI/AAMI recommends a minimum of ten changes of air per hour. If the vapor is irritating to the eyes and nose the threshold limit value is probably exceeded and additional ventilation may be needed. When required, Refer to the ACGIH document, “Industrial Ventilation, a Manual of Recommended Practices” for details about ventilation.
Personal Respirator: Not required unless the threshold limit value for glutaraldehyde is exceeded. In case of emergency, or when exposure levels are unknown, use a half face or full face respirator with organic vapor cartridges.
Skin protection: Chemical resistant gloves are recommended. Latex gloves are not impervious to glutaraldehyde and are not as appropriate as nitrile gloves.
Eye Protection: Laboratory safety goggles, safety glasses or face shield are required.

Section IX - Physical and Chemical Properties

Boiling Point: 100 °C
Vapor pressure (mm Hg): 18 @ 20 °C
Vapor Density (air = 1): 0.6
Density: About 1.01 g/ml
Evaporation Rate (water = 1): 1
Solubility: Infinitely miscible with water
Appearance and Odor: A clear, yellowish liquid with the characteristic odor of glutaraldehyde.

Section X - Stability and Reactivity

Stability: Freezes at low temperature.
Hazardous Decomposition Products: Nothing unusual.
Hazardous polymerization: Will not occur.
Incompatibilities: Nothing unusual.
Conditions to avoid: Excessive cold/heat and light. High pH catalyzes an aldol type polymerization that is exothermic but not expected to be violent.

Section XI - Toxicological Information

Toxicity: The chronic toxicity of this product is unknown but may include sensitization in sensitive individuals. The toxic effects of glutaraldehyde are believed to be the result of its ability to cross link proteins, which is the same property responsible for its antimicrobial effect. The manufacturer is unaware of any target organ toxicity.
Mutagenicity: MCC is unaware of any evidence that the product is mutagenic or teratogenic. However the effects of these products, glutaraldehyde based disinfectants, are not well investigated and we recommend that pregnant customers use an abundance of caution with these products.
Oral LD_{50} for rats = 134 mg/kg for pure glutaraldehyde
Oral LD_{50} for mouse = 100 mg/kg for pure glutaraldehyde

Ingredient	Known Carcinogenicity?	NTP?	Anticipated?	IARC Category
Glutaraldehyde	no	no	no	none

Wavicide-01 is not a carcinogen or suspected carcinogen.

Section XII - Ecological Information

Environmental Fate: Biodegradable. Wavicide-01 is biodegradable when diluted to a level such that it is not microbicidal.
Environmental Toxicity: May be toxic to fish.

Section XIII - Disposal Considerations

Normally not restricted but local governments may restrict the amounts of aldehydes that can be flushed down the drain. In localities where drain disposal is restricted the product may usually be neutralized with glycine or sodium bisulfite (about 50 grams per liter) and then flushed down the drain. Dispose of contents and container in accordance with all government regulations.

Section XIV - Transportation Information

Not regulated.

Section XV - Regulatory Information

Chemical Inventory Status

Ingredient	TSCA	EC
glutaraldehyde	Yes	Yes

Federal, State and International Regulations

	SARA 302		SARA 313		RCRA	TSCA	
Ingredient	RQ	TPQ	List	Category	261.33	8(D)	Ca. Prop 65
glutaraldehyde	No	No	No	No	No	No	No

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
SARA 311/312: Acute: None, Chronic: None

Section XVI - Other Information

This information is believed to be correct but is not waranteed as such, nor does it purport to be all inclusive.
Revision Date: Jan. 15, 2018

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Xylocaine/Xylocaine-MPF**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	January 08, 2009
SDS Revision Date:	June 01, 2015

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. Category 1.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects: Possible adverse reactions include: lightheadedness, nervousness, drowsiness, bradycardia, hypotension, and allergic reactions. Occupational exposure has not been fully investigated.

Eye: Contact with eyes may cause irritation.

Signs/Symptoms: Possible adverse reactions include: lightheadedness, nervousness, drowsiness, bradycardia, hypotension, and allergic reactions. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Individuals with a known history of hypersensitivity to local anesthetics of the amide type or to other components of Xylocaine®/Xylocaine®-MPF.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Lidocaine Hydrochloride	137-58-6	0.5 %, 1 %, 1.5 %, and 2 %	
Sodium Chloride	7647-14-5	For Isotonicity	
Methylparaben	99-76-3	1 mg/mL	

Note: Xylocaine®-MPF does not contain methylparaben

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Should be stored at room temperature, approximately 25°C (77°F). Protect from light.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended topical purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.

Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Odor:	Odorless.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	17 mmHg at 20°C
Percent Volatile:	Not established.
pH:	Approximately 6.5 (5.0-7.0)
Molecular Formula:	Mixture
Molecular Weight:	288.82
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Incompatible Materials:	Water reactive materials.

SECTION 11 : TOXICOLOGICAL INFORMATION

Lidocaine Hydrochloride :

Acute Toxicity:	LD50 IV Rat: 21 mg/kg LD50 IV Mouse: 15 mg/kg

Lidocaine Hydrochloride :

RTECS Number:	AN7525000
Ingestion:	Oral - Rat LD50: 317 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 220 mg/kg [Behavioral - Convulsions or effect on seizure threshold Behavioral - Rigidity (including catalepsy) Lungs, Thorax, or Respiration - Respiratory stimulation]
Other Toxicological Information:	Intravenous. - Human TDLo: 23 mg/kg [Behavioral - muscle contraction or spasticity Lungs, Thorax, or Respiration - dyspnea] Intravenous. - Mouse LD50: 20 mg/kg [Behavioral - convulsions or effect on seizure threshold Vascular - BP lowering not characterized in autonomic section Lungs, Thorax, or Respiration - other changes] Intravenous. - Rabbit LDLo: 41 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Guinea pig LDLo: 65 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 39.4 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat LD50: 18 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat TDLo: 5 mg/kg [Vascular - BP lowering not characterized in autonomic section] Intravenous. - Rat TDLo: 2343 ug/kg/5M [Cardiac - change in rate] Intravenous. - Rat TDLo: 4688 ug/kg/5M [Vascular - BP lowering not characterized in autonomic section] Intravenous. - Rabbit TDLo: 3 mg/kg [Cardiac - change in rate Cardiac - cardiac output Vascular - BP lowering not characterized in autonomic section] Subcutaneous - Rat LD50: 335 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50: 238 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Guinea pig LD50: 120 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Human TDLo: 33.3 ug/kg [Behavioral - analgesia] Subcutaneous - Mouse TDLo: 50 mg/kg [Peripheral Nerve and Sensation - local anesthetic] Subcutaneous - Mouse TDLo: 150 mg/kg [Behavioral - convulsions or effect on seizure threshold] Intraperitoneal. - Rat LD50: 133 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - other changes] Intraperitoneal. - Mouse LD50: 102 mg/kg [Peripheral Nerve and Sensation - local anesthetic Behavioral - convulsions or effect on seizure threshold Behavioral - ataxia] Intraperitoneal. - Rat TDLo: 2 mg/kg [Blood - other changes]

Sodium Chloride :

RTECS Number:	VZ4725000
Eye:	Eye - Rabbit Standard Draize test.: 10 mg [Moderate]

Skin:	Administration onto the skin - Rabbit LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit Standard Draize test.: 50 mg/24H [mild] Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]
Inhalation:	Inhalation - Rat LC50: >42 gm/m3/1H [Details of toxic effects not reported other than lethal dose value]
Ingestion:	Oral - Mouse LD50: 4 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit LDLo: 1100 mg/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - muscle contraction or spasticity Cardiac - other changes] Intravenous. - Guinea pig LDLo: 300 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse TDLo: 2.1 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)] Intravenous. - Rabbit LDLo: 1.5 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)] Subcutaneous - Rat LDLo: 3500 mg/kg [Behavioral - irritability] Subcutaneous - Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Guinea pig LDLo: 2160 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Skin and Appendages - dermatitis, irritative (after systemic exposure)] Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death] Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Subcutaneous - Mouse TDLo: 2500 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)] Subcutaneous - Mouse TDLo: 13440 mg/kg [Reproductive - Fertility - abortion] Intraperitoneal. - Mouse LD50: 2602 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD50: 2600 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LDLo: 3.72 gm/kg [Behavioral - tremor Behavioral - convulsions or effect on seizure threshold] Intraperitoneal. - Rat TDLo: 1710 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Intraperitoneal. - Rat TDLo: 10 gm/kg [Reproductive - Effects on Newborn - behavioral] Intraperitoneal. - Rat Cytogenetic analysis: 2338 mg/kg

Methylparaben :

RTECS Number:	DH2450000
Skin:	Administration onto the skin - Rabbit Standard Draize test.: 0.1 mL/24H Administration onto the skin - Rabbit Standard Draize test.: 0.5 mL/21D (Intermittent) Administration onto the skin - Rat TDLo: 374.92 gm/kg/13W (Intermittent) [Nutritional and Gross Metabolic - Weight loss or decreased weight gain Blood - Other changes]
Ingestion:	Oral - Mouse LD50: >8 gm/kg [Peripheral Nerve and Sensation - Flaccid paralysis without anesthesia (usually neuromuscular blockage) Behavioral - Ataxia] Oral - Mouse LD50: >8000 mg/kg [Behavioral - Ataxia] Oral - Rat LD50: 2100 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Mouse TDLo: 100 mg/kg [Vascular - shock Lungs, Thorax, or Respiration - respiratory depression] Intravenous. - Mouse TDLo: 2.5 mg/kg [Lungs, Thorax, or Respiration - tumors] Subcutaneous - Mouse TDLo: 165 mg/kg [Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression] Subcutaneous - Mouse LD50: 1.2 gm/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LD50: >500 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse TDLo: 49.5 mg/kg/3D (intermittent) [Related to Chronic Data - changes in uterine weight] Subcutaneous - Mouse TDLo: 165 mg/kg/3D (intermittent) [Reproductive - Maternal Effects - uterus, cervix, vagina Related to Chronic Data - changes in uterine weight] Intraperitoneal. - Mouse LD50: 960 mg/kg [Peripheral Nerve and Sensation - flaccid paralysis without anesthesia (usually neuromuscular blockage) Behavioral - somnolence (general depressed activity) Behavioral - ataxia] Intraperitoneal. - Mouse LD50: 125 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD50: 960 mg/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	NA Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Lidocaine Hydrochloride :

TSCA Inventory Status:	Listed
EINECS Number:	205-302-8
Canada DSL:	Listed

Sodium Chloride :

TSCA Inventory Status:	Listed
EINECS Number:	231-598-3
Canada DSL:	Listed

Methylparaben :

TSCA Inventory Status:	Listed
EINECS Number:	202-785-7
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	2
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	X

SDS Creation Date:	January 08, 2009
SDS Revision Date:	June 01, 2015

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