Hanover Family
5/23/2021

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sanofi pasteur
The vaccines division of sanofi-aventis Group

Material Safety Data Sheet for Sanofi Pasteur Vaccines and Biologics

Contact: Customer Service – 1-800-822-2463 **Effective Date: February 3, 2011**

NFPA Rating (0,0,0)

Product:

ActHIB®, Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)

ADACEL®, Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed

DAPTACEL®, Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

DECAVAC®, Tetanus and Diphtheria Toxoids Adsorbed (For 7 years of age and older)

DT, Diphtheria and Tetanus Toxoids Adsorbed USP (For Pediatric Use up to 7 years of age)

Fluzone®, Influenza Virus Vaccine (All presentations)

Imogam® Rabies-HT, Rabies Immune Globulin (Human) USP Heat Treated

IMOVAX® RABIES, Rabies Vaccine

IPOL®, Poliovirus Vaccine Inactivated

Menactra®, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine

Menomune®-A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined

Pentacel®, Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine

Tetanus Toxoid Adsorbed

TheraCys®, BCG Live (Intravesical)

Tripedia®, Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

sanofi pasteur . Discovery Drive . Swiftwater, Pennsylvania 18370 . Tel.: 1-800-VACCINE (1-800-822-2463) . www.sanofipasteur.us
Sanofi Pasteur Inc.

Tubersol®, Tuberculin Purified Protein Derivative (Mantoux)

Typhim Vi®, Typhoid Vi Polysaccharide Vaccine

YF-VAX®, Yellow Fever Vaccine

Diluent:

Diluent for reconstitution of ActHIB vaccine

Diluent for reconstitution of IMOVAX RABIES vaccine

Diluent for reconstitution of Menomune vaccine

Diluent for reconstitution of TheraCys BCG

Diluent for reconstitution of YF-VAX vaccine

We have conducted a hazard evaluation of the constituents of the above products in accordance with OSHA's Hazard Communication Standard [29 CFR 1910.1200(d)]. It has been determined that the product or diluent ingredients do not pose a physical or health hazard at the percentages present in the mixtures based on the guidelines set by OSHA's Hazard Communication Standard. Therefore, as of this date, we are not required under OSHA Federal Regulations to distribute a Material Safety Data Sheet for these products.

For more information concerning product safety refer to the prescribing information or call Customer Service at the phone number listed above.

SAFETY DATA SHEET

1. Identification

Product identifier **BOOSTRIX**

Other means of identification

Synonyms BOOSTRIX DTPa * BOOSTRIX DTPa JERINGA * BOOSTRIX FERTIGSPRITZE * BOOSTRIX INJECTION * BOOSTRIX JERINGA PRELLENADA * BOOSTRIX PFS * BOOSTRIX SIRINGA PRERIEMPITA * BOOSTRIX Tdpa IMPFSTOFF ZUR AUFFRISCHUNG * REFORTRIX * DIPHTHERIA, TETANUS AND ACELLULAR PERTUSSIS ADSORBED 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	%
ALUMINIUM HYDROXIDE	AF 260 * ALCOA 331 * ALCOA C 30BF * 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 * ALUSAL * AMBEROL ST 140F * AMPHOJEL * BACO AF 260 * BRITISH ALUMINUM AF 260 * C 31 * C 33 * C 31C * C 4D * C 31F * C-31-F * C.I. 77002 * GHA 331 * GHA 332 * H 46 * HIGILITE * HIGILITE H 32 * HIGILITE H 42 * HIGILITE H 31S * HYCHOL 705 * HYDRAL 705 * HYDRAL 710 * HYDRATED ALUMINA * LIQUIGEL * MARTINAL * P 30BF * PGA * TRIHYDRATED ALUMINA * TRIHYDROXYALUMINUM	21645-51-2	1
SODIUM CHLORIDE	COMMON SALT * HALITE * ROCK SALT * SODIUM MONOCHLORIDE * SALT * SEA SALT * TABLE SALT * SODIUM CHLORIDE (NaCl) * ClNa * BULK INDUSTRIAL CRUDE SOLAR * SALT, WHITE CRYSTALS, SOLAR * OHS21105 * RTECS VZ4725000 * 329 (GW ACN)	7647-14-5	1
DIPHTHERIA TOXOID		Unassigned	<1
FILAMENTOUS HAEMAGGLUTININ		Unassigned	<1
PERTACTIN (69 KDA OUTER MEMBRANE PROTEIN-69K)		Unassigned	<1
PERTUSSIS TOXIN	HISTAMINE-SENSITIZING FACTOR * IAP * ISLET ACTIVATING PROTEIN * LYMPHOCYTOSIS-PROMOTING FACTOR	70323-44-3	<1
TETANUS TOXOID		Unassigned	<1
Other components below reportable levels			91

*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 Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Eye contact Rinse immediately with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth thoroughly. Get medical advice/attention if you feel unwell. Do not induce vomiting.

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 centre.

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.

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. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	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. Prevent entry into waterways, sewer, basements or confined areas. 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	Avoid prolonged exposure. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Do not freeze. Dispose of properly if frozen.

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
PERTUSSIS TOXIN (CAS 70323-44-3)	OHC	5	PROVISIONAL

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
ALUMINIUM HYDROXIDE (CAS 21645-51-2)	TWA	1 mg/m3	Respirable fraction.

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

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 suitable protective 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.

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.
Other information	
Percent volatile	91 % estimated

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. 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.
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 Health injuries are not known or expected under normal use.

Components	Species	Test Results
SODIUM CHLORIDE (CAS 7647-14-5)		
Acute		
Oral		
LD50	Rat	3000 mg/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.

Respiratory or skin sensitization

Respiratory sensitization Not established.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Contains no ingredient listed as toxic to reproduction

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 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
SODIUM CHLORIDE (CAS 7647-14-5)			
Aquatic			
Acute			
Algae	EC50	Algae (Nitscheria linearis)	2430 mg/l, 5 days
Crustacea	EC50	Water flea (Daphnia magna)	3310 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Juvenile Lepomis macrochirus)	1295 mg/l, 96 hours Static test
		Fathead minnow (Juvenile Pimephales promelas)	6390 mg/l, 96 hours Static test
		Goldfish (Adult Carassius auratus)	7000 mg/l, 96 hours
		Mosquito fish (Adult Gambusia affinis)	17550 mg/l, 96 hours Static test

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

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

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 - 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)

Chemical name	CAS number	% by wt.
2-PHENOXYETHANOL	122-99-6	1

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
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	07-02-2014
Revision date	07-02-2014
Version #	12
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 0 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 0 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: Ingredients Physical & Chemical Properties: Transport Information: Material Transportation Information Regulatory Information: United States GHS: Classification

SAFETY DATA SHEET

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

Product Identifier

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

Trade Name: Not established
Chemical Family: Cephalosporin antibiotic

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

Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

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

Precautionary Statements:

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

Other Hazards

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

Note:

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

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

Additional Information:

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

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

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

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

Skin Contact:

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

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

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

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

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

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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

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

7. HANDLING AND STORAGE

Precautions for Safe Handling

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

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Ceftriaxone sodium

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

Exposure Controls

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

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

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

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

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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

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

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

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

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

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

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

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

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

Ceftriaxone sodium

Rat Oral LD50 > 10 g/kg

Rat Subcutaneous LD50 > 5g/kg

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

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

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

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

Ceftriaxone sodium

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

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

Ceftriaxone sodium

11. TOXICOLOGICAL INFORMATION

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

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

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

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

15. REGULATORY INFORMATION

Ceftriaxone sodium

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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

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

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

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

End of Safety Data Sheet

SAFETY DATA SHEET

1. Identification

Product identifier — **Children's Benadryl Allergy Liquid; Children's Benadryl Allergy Perfect Measure**

Other means of identification

Product code — McNeil C-1165, MCHC-BDRCHALL

Recommended use — Relief from allergies for children.

Recommended restrictions — None known.

Manufacturer / Importer / Supplier / Distributor information

Company name — McNeil Consumer Healthcare, Division of McNeil-PPC, Inc.

Address — 7050 Camp Hill Rd.
Fort Washington, PA
19034-2299

Telephone — (215) 273-7000

Emergency telephone 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. Hazard(s) identification

Physical hazards — Not classified.

Health hazards — Not classified.

OSHA defined hazards — Not classified.

Label elements

Hazard symbol — None.

Signal word — None.

Hazard statement — The product does not meet the criteria for classification.

Precautionary statement

Prevention — Not applicable.

Response — No specific first aid measures noted.

Storage — Store at 20 – 25 ºC (68 - 77ºF).

Disposal — Dispose of contents in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) — Not classified.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Sucrose	57-50-1	40
Glycerin	56-81-5	1-5
Diphenhydramine HCl	147-24-0	0.1-1

Composition comments — All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

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

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.

Eye contact — In case of 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.

Ingestion — If symptomatic, seek medical advice.

Most important symptoms/effects, acute and delayed — Exposed individuals may experience eye tearing, redness, and discomfort.

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.

Special 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 Wear appropriate personal protective equipment (See Section 8).

Methods and materials for containment and cleaning up Wipe up with absorbent material (e.g. cloth, fleece).

Environmental precautions Prevent from entering into soil, ditches, sanitary sewers, waterways and/or groundwater.

7. Handling and storage

Precautions for safe handling Avoid contact with eyes. Wash hands after handling. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store between 68ºF – 77ºF (20ºC - 25ºC). Protect from light. Store in outer carton until contents are used.

8. Exposure controls/personal protection

Occupational exposure limits

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

Components	Type	Value	Form
Glycerin (CAS 56-81-5)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
Sucrose (CAS 57-50-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Glycerin (CAS 56-81-5)	TWA	10 mg/m3	Mist.
Sucrose (CAS 57-50-1)	TWA	10 mg/m3	

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

Exposure guidelines Diphenhydramine HCl, CAS # 147-24-0
OEL-TWA = 139 µg/m3

Appropriate 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 protection

Hand protection Use protective gloves.

Other 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 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. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.
Thermal hazards	Not applicable.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	Red colored solution.
Physical state	Liquid.
Form	Liquid.
Color	Red.
Odor	Fruity.
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)	Miscible in water.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is non-reactive under normal conditions of use, storage and transport.
Chemical stability	Stable under normal temperature conditions.
Possibility of hazardous reactions	Hazardous reactions do not occur. Hazardous polymerization does not occur.
Conditions to avoid	Elevated temperatures.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Expected to be a low ingestion hazard.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	This product is not expected to be a skin hazard.
Eye contact	May cause eye irritation on direct contact.
Symptoms related to the physical, chemical and toxicological characteristics	Exposed individuals may experience eye tearing, redness, and discomfort.

Information on toxicological effects

Acute toxicity Under normal conditions of intended use, this material does not pose a risk to health.

Components	Species	Test Results
Diphenhydramine HCl (CAS 147-24-0)		
Acute		
Oral		
LD50	Rat	700 mg/kg
Sucrose (CAS 57-50-1)		
Acute		
Oral		
LD50	Rat	29700 mg/kg

Skin corrosion/irritation	Skin irritation is not anticipated when used normally.
Serious eye damage/eye irritation	May cause eye irritation.
Respiratory sensitization	No sensitizing effects known.
Skin sensitization	This product is not expected to cause skin sensitization.
Germ cell mutagenicity	This product is not expected to cause mutagenic or genotoxic effects.
Carcinogenicity	Not available.
Reproductive toxicity	Not available.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not available.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	Not available.
Bioaccumulative potential	No data available for this product.
Mobility in soil	Not available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations.
Local disposal regulations	Dispose of in accordance with local regulations.
Hazardous waste code	Hazardous waste code should be determined in accordance with hazardous waste regulatory authorities.
Waste from residues / unused products	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

US federal regulations

This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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

Not regulated.

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

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

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

SARA 302 Extremely hazardous substance

No

SARA 311/312 Hazardous chemical

No

Other federal regulations

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

Not regulated.

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

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

Food and Drug Administration (FDA)

Not regulated.

US state regulations

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

US. Massachusetts RTK - Substance List

Glycerin (CAS 56-81-5)
Sucrose (CAS 57-50-1)

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Glycerin (CAS 56-81-5)
Sucrose (CAS 57-50-1)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

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

Not listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

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

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

Issue date 21-June-2013

Revision date -

Version # 01

NFPA Ratings

Disclaimer

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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

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.

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.

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.

SANOFI PASTEUR

Material Safety Data Sheet for Sanofi Pasteur Vaccines and Biologics

Contact: Customer Service – 1-800-822-2463 **Effective Date: June 2013**

NFPA Rating (0,0,0)

Product:

ActHIB®, Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)

Adacel®, Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed

DAPTACEL®, Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

DECAVAC®, Tetanus and Diphtheria Toxoids Adsorbed (For 7 years of age and older)

DT, Diphtheria and Tetanus Toxoids Adsorbed (For Pediatric Use)

Fluzone®, Influenza Virus Vaccine (All presentations including Fluzone High-Dose, Fluzone Intradermal and Fluzone Quadrivalent vaccines)

Imogam® Rabies-HT, Rabies Immune Globulin (Human) USP, Heat Treated

IMOVAX® RABIES, Rabies Vaccine

IPOL®, Poliovirus Vaccine Inactivated

Menactra®, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine

Menomune®- A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined

Pentacel®, Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine

TENIVAC™, Tetanus and Diphtheria Toxoids Adsorbed

Tetanus Toxoid Adsorbed

TheraCys®, BCG Live (Intravesical)

TUBERSOL®, Tuberculin Purified Protein Derivative (Mantoux)

Typhim Vi®, Typhoid Vi Polysaccharide Vaccine

YF-VAX®, Yellow Fever Vaccine

Discovery Drive, Swiftwater, Pennsylvania 18370 - Tel.: 1-800-VACCINE (800-822-2463) - www.sanofipasteur.us
SANOFI PASTEUR Inc.

SANOFI PASTEUR

Diluent:

Diluent for reconstitution of ActHIB vaccine (0.4% Sodium Chloride)

Diluent for reconstitution of IMOVAX RABIES vaccine (sterile water)

Diluent for reconstitution of Menomune-A/C/Y/W-135 vaccine (sterile pyrogen-free distilled water for single-dose vial or sterile pyrogen-free distilled water with thimerosal for multiple-dose vial)

Diluent for reconstitution of YF-VAX vaccine (Sodium Chloride for Injection)

We have conducted a hazard evaluation of the constituents of the above products in accordance with OSHA's Hazard Communication Standard [29 CFR 1910.1200(d)]. It has been determined that the product or diluent ingredients do not pose a physical or health hazard at the percentages present in the mixtures based on the guidelines set by OSHA's Hazard Communication Standard. Therefore, as of this date, we are not required under OSHA Federal Regulations to distribute a Material Safety Data Sheet for these products.

For more information concerning product safety refer to the prescribing information or call Customer Service at the phone number listed above.

SAFETY DATA SHEET

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

Product Identifier

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

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

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

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

Details of the Supplier of the Safety Data Sheet

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

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

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

Label Elements

Signal Word: Danger

Hazard Statements:
H360D - May damage the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P314 - Get medical attention/advice if you feel unwell
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

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

Note:

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Ketorolac tromethamine	74103-07-4	Not Listed	Acute Tox.3 (H301) STOT RE 2 (H373) Repr.1A (H360D)	1.5-3.0
Ethanol	64-17-5	200-578-6	Flam. Liq. 2 (H225)	7 - 12
Hydrochloric Acid	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	**
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr.1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

Additional Information:

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

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

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

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

Skin Contact:

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

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

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

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

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

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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

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

7. HANDLING AND STORAGE

Precautions for Safe Handling

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

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Ethanol

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

Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	2 ppm

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sodium hydroxide

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sodium chloride

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

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection:	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	**Color:**	Clear to light yellow
Odor:	Alcohol Slight	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
Solubility:	Soluble: Water
pH:	6.9-7.9
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

9. PHYSICAL AND CHEMICAL PROPERTIES

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

Decomposition Temperature (°C):	No data available.
Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Specific Gravity:	0.991
Viscosity:	No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	55 (ethanol)
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available
Polymerization:	Will not occur

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:	The information included in this section describes the potential hazards of the individual ingredients.
Short Term:	Accidental ingestion may cause effects similar to those seen in clinical use. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

11. TOXICOLOGICAL INFORMATION

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

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

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

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

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

Sodium hydroxide
Mouse IP LD50 40 mg/kg

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

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Ethanol
Eye Irritation Rabbit Severe

Hydrochloric Acid
Skin Irritation Severe
Eye Irritation Severe

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

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

11. TOXICOLOGICAL INFORMATION

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

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

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

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

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

Ethanol
IARC: Group 1 (Carcinogenic to Humans)

Hydrochloric Acid
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:

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

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

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

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

Ketorolac tromethamine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

Ethanol

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

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed

15. REGULATORY INFORMATION

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

Sodium hydroxide

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

Water for injection

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

Sodium chloride

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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor

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

Revision date: 03-Aug-2016
Product Stewardship Hazard Communication

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

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

End of Safety Data Sheet

SAFETY DATA SHEET

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

Product Identifier

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

Trade Name: Lignocaine Injection
Synonyms: Lidocaine
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product anesthetic agent

Details of the Supplier of the Safety Data Sheet

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

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

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

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

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Lidocaine Hydrochloride	73-78-9	200-803-8	Acute Tox.4 (H302)	1-2
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**

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

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

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

4. FIRST AID MEASURES

Description of First Aid Measures

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

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

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

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

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

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

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Additional Consideration for Large Spills:	Contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal.

7. HANDLING AND STORAGE

Precautions for Safe Handling

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

Conditions for Safe Storage, Including any Incompatibilities

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Sodium chloride

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

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit:	2 mg/m^3
Australia PEAK	2 mg/m^3
Austria OEL - MAKs	2 mg/m^3
Bulgaria OEL - TWA	2.0 mg/m^3
Czech Republic OEL - TWA	1 mg/m^3
Estonia OEL - TWA	1 mg/m^3
France OEL - TWA	2 mg/m^3
Greece OEL - TWA	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Japan - OELs - Ceilings	2 mg/m^3
Latvia OEL - TWA	0.5 mg/m^3
OSHA - Final PELS - TWAs:	2 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Poland OEL - TWA	0.5 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	1 mg/m^3
Switzerland OEL -TWAs	2 mg/m^3

HYDROCHLORIC ACID

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA	5 ppm 7.6 mg/m^3
Switzerland OEL -TWAs	2 ppm 3.0 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3

Lidocaine Hydrochloride

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

Sodium chloride

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

Exposure Controls

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

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

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

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

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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

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

Decomposition Temperature (°C): No data available.

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

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

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

Short Term: Harmful if swallowed May cause mild eye irritation. May cause slight skin irritation. (based on components) Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

Known Clinical Effects: Adverse effects associated with therapeutic use include dizziness, nervousness, agitation, drowsiness, apprehension, euphoria, blurred/double vision, slurred speech, tremors, convulsions, and seizure. Respiratory depression and arrest may follow. Other, more serious effects seen with IV use of this drug, particularly when it is administered rapidly, are cardiovascular collapse, central nervous system depression, and/or hypotension.

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

Lidocaine Hydrochloride

11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 317 mg/kg
Rat Para-periosteal LD50 25mg/kg
Rat Intraperitoneal LD50 133mg/kg
Mouse Oral LD50 292mg/kg
Mouse Intravenous LD50 19.5mg/kg

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

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

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

Lidocaine Hydrochloride
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

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

Lidocaine Hydrochloride

Embryo / Fetal Development	Rat	Subcutaneous	30 mg/kg	NOAEL	Not teratogenic
Embryo / Fetal Development	Rat	Intraperitoneal	56 mg/kg	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Intraperitoneal	72 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Intravenous	500 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Intraperitoneal	6 mg/kg	LOAEL	Developmental toxicity

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

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

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

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

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

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

Lidocaine Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-803-8

Sodium chloride

15. REGULATORY INFORMATION

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

Water for injection

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

SODIUM HYDROXIDE

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

HYDROCHLORIC ACID

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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

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

Reasons for Revision:	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.
Revision date:	26-Jul-2017
	Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

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

End of Safety Data Sheet

SAFETY DATA SHEET

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

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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

2. HAZARD(S) IDENTIFICATION

Emergency Overview

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

U.S. OSHA GHS Classification

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

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

Label Element(s)

Pictogram	NA
Signal Word	NA
Hazard Statement(s)	NA
Precautionary Statement(s) Prevention	Do not breathe vapor or spray Wash hands thoroughly after handling
Response	Get medical attention if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

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

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

4. FIRST AID MEASURES

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

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

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

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

5. FIRE FIGHTING MEASURES

Flammability None anticipated for this aqueous product.

Fire & Explosion Hazard None anticipated for this aqueous product.

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

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

6. ACCIDENTAL RELEASE MEASURES

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

7. HANDLING AND STORAGE

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

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

Special Precautions No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

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

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

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

9. PHYSICAL/CHEMICAL PROPERTIES

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

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

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

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

LD 50: Dosage that produces 50% mortality.

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

11. TOXICOLOGICAL INFORMATION: continued

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

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORTATION INFORMATION

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

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

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

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

GHS/CLP Classification*

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

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

Prevention

Do not breathe vapor or spray
Wash hands thoroughly after handling

Response

Get medical attention if you feel unwell.

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

EU Classification*

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

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

16. OTHER INFORMATION

Notes:

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

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

Disclaimer:
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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 Multi-Enzymatic Cleanser Fresh Mint Fragrance
MFR #: 53-28501

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

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

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

PRODUCT DESCRIPTION: A surfactant and multi-enzyme formulation for instrument cleaning.

2. HAZARDS IDENTIFICATION

Appearance Clear turquoise liquid **Physical State** Liquid **Odor** Spearmint/Eucalyptus

Classification

Serious eye damage/eye irritation	Category 2

Signal Word
Warning

Hazard Statements
Causes serious eye irritation

Precautionary Statements - Prevention
Wash face, hands and any exposed skin thoroughly after handling
Wear eye/face protection

Precautionary Statements - Response
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
Get medical attention if irritation occurs

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%
Isopropyl alcohol	67-63-0	<5
Monoethanolamine	141-43-5	<2
Propylene Glycol	57-55-6	<5

4. FIRST-AID MEASURES

First Aid Measures

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention if irritation occurs.
Skin Contact	Wash hands thoroughly after handling.
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call Poison Control or doctor/physician.
Ingestion	Dilute by giving a large amount of water. Allow vomiting to occur, then get medical attention.

Most important symptoms and effects

Symptoms	Eye contact may cause redness or burning sensation. Prolonged or repeated skin contact may cause irritation. May cause gastrointestinal disturbance.

Indication of any immediate medical attention and special treatment needed

Notes to Physician	Treat symptomatically.

5. FIRE-FIGHTING MEASURES

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

Unsuitable Extinguishing Media	Not determined.

Specific Hazards Arising from the Chemical
Non-flammable.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions	Use personal protective equipment as required.
Environmental Precautions	See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for Clean-Up	Small spills (less than 1 gallon) may be washed down a drain with lots of water or cleaned up and disposed of into a sanitary sewer system. Large spills (more than 1 gallon) should be contained and collected (by absorption [sand, clay, or other absorbent material] or vacuuming) then disposed of properly.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on Safe Handling Wash thoroughly after handling. Use personal protection recommended in Section 8. Avoid breathing vapors or mists.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Do not contaminate food or feed stuffs. Do not reuse container. Keep out of the reach of children.

Incompatible Materials None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Isopropyl alcohol 67-63-0	STEL: 400 ppm TWA: 200 ppm	TWA: 400 ppm TWA: 980 mg/m^3 (vacated) TWA: 400 ppm (vacated) TWA: 980 mg/m^3 (vacated) STEL: 500 ppm (vacated) STEL: 1225 mg/m^3	IDLH: 2000 ppm TWA: 400 ppm TWA: 980 mg/m^3 STEL: 500 ppm STEL: 1225 mg/m^3
Propylene Glycol 57-55-6	TWA: 10mg/m3	TWA: 10mg/m3	-
Monoethanolamine 141-43-5	STEL: 6 ppm TWA: 3 ppm	TWA: 3 ppm TWA: 6 mg/m^3 (vacated) TWA: 3 ppm (vacated) TWA: 8 mg/m^3 (vacated) STEL: 6 ppm (vacated) STEL: 15 mg/m^3	IDLH: 30 ppm TWA: 3 ppm TWA: 8 mg/m^3 STEL: 6 ppm STEL: 15 mg/m^3

Appropriate engineering controls

Engineering Controls Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/Face Protection Risk of contact: Wear approved safety goggles.

Skin and Body Protection For prolonged or repeated skin contact use suitable protective gloves.

Respiratory Protection No protection is ordinarily required under normal conditions of use and with adequate ventilation.

General Hygiene Considerations Do not get in eyes. Keep away from food and drink.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid		
Appearance	Clear turquoise liquid	**Odor**	Spearmint/Eucalyptus
Color	Turquoise	**Odor Threshold**	Not determined

Property	**Values**	**Remarks • Method**
pH	7.5-8.5 (concentrate)	
Melting Point/Freezing Point	Not established	

Boiling Point/Boiling Range	100 °C / 212 °F
Flash Point	Not flammable
Evaporation Rate	Not established
Flammability (Solid, Gas)	n/a-liquid
Upper Flammability Limits	Not available
Lower Flammability Limit	Not available
Vapor Pressure	Not established
Vapor Density	Not established
Specific Gravity	1.00-1.04
Water Solubility	Completely soluble
Solubility in other solvents	Not determined
Partition Coefficient	Not determined
Autoignition Temperature	Not determined
Decomposition Temperature	Not determined
Kinematic Viscosity	Not determined

Property	**Values**	**Remarks • Method**
Dynamic Viscosity	Not determined	
Explosive Properties	Not determined	
Oxidizing Properties	Not determined	

10. STABILITY AND REACTIVITY

Reactivity
Not reactive under normal conditions.

Chemical Stability
Stable under recommended storage conditions.

Possibility of Hazardous Reactions
None under normal processing.

Hazardous Polymerization Hazardous polymerization does not occur.

Conditions to Avoid
Keep out of reach of children.

Incompatible Materials
None known.

Hazardous Decomposition Products
None known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Eye Contact Causes serious eye irritation.

Skin Contact Avoid contact with skin.

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Ingestion Do not taste or swallow.

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Isopropyl alcohol 67-63-0	= 4396 mg/kg (Rat)	= 12800 mg/kg (Rat) = 12870 mg/kg (Rabbit)	= 72.6 mg/L (Rat) 4 h
Propylene Glycol 57-55-6	= 20000 mg/kg (Rat)	= 20800 mg/kg (Rabbit)	-
Monoethanolamine 141-43-5	= 1720 mg/kg (Rat)	= 1 mL/kg (Rabbit) = 1025 mg/kg (Rabbit)	-

Information on physical, chemical and toxicological effects

Symptoms Please see section 4 of this SDS for symptoms.

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

Sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Carcinogenicity Isopropyl Alcohol (IPA) is listed as an IARC Monograph Group 3 chemical. However, IARC Group 3 chemicals are "not classifiable as human carcinogens".

Chemical Name	ACGIH	IARC	NTP	OSHA
Isopropyl alcohol 67-63-0		Group 3		X

Legend

IARC (International Agency for Research on Cancer)
Group 3 IARC components are "not classifiable as human carcinogens"
OSHA (Occupational Safety and Health Administration of the US Department of Labor)
X - Present

Numerical measures of toxicity
Not determined

12. ECOLOGICAL INFORMATION

Ecotoxicity
An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Isopropyl alcohol 67-63-0	1000: 96 h Desmodesmus subspicatus mg/L EC50 1000: 72 h Desmodesmus subspicatus mg/L EC50	9640: 96 h Pimephales promelas mg/L LC50 flow-through 11130: 96 h Pimephales promelas mg/L LC50 static 1400000: 96 h Lepomis macrochirus µg/L LC50		13299: 48 h Daphnia magna mg/L EC50
Propylene Glycol 57-55-6	19000: 96 h Pseudokirchneriella subcapitata mg/L EC50	51600: 96 h Oncorhynchus mykiss mg/L LC50 static 41 - 47: 96 h Oncorhynchus mykiss mL/L LC50 static 51400: 96 h Pimephales promelas mg/L LC50 static 710: 96 h Pimephales promelas mg/L LC50		10000: 24 h Daphnia magna mg/L EC50 1000: 48 h Daphnia magna mg/L EC50 Static

Monoethanolamine 141-43-5	15: 72 h Desmodesmus subspicatus mg/L EC50	227: 96 h Pimephales promelas mg/L LC50 flow-through 3684: 96 h Brachydanio rerio mg/L LC50 static 300 - 1000: 96 h Lepomis macrochirus mg/L LC50 static 114 - 196: 96 h Oncorhynchus mykiss mg/L LC50 static 200: 96 h Oncorhynchus mykiss mg/L LC50 flow-through		65: 48 h Daphnia magna mg/L EC50

Persistence/Degradability
Not determined

Bioaccumulation
Not determined

Mobility

Chemical Name	Partition Coefficient
Isopropyl alcohol 67-63-0	0.05
Monoethanolamine 141-43-5	-1.91

Other Adverse Effects
Not determined

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods

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

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

California Hazardous Waste Status

Chemical Name	California Hazardous Waste Status
Isopropyl alcohol 67-63-0	Toxic Ignitable

14. TRANSPORT INFORMATION

Note Please see current shipping paper for most up to date shipping information, including exemptions and special circumstances.

DOT Not regulated

IATA Not regulated

IMDG Not regulated

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	<5	1.0

US State Regulations

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Isopropyl alcohol 67-63-0	X	X	X
Propylene Glycol 57-55-6	X		X
Monoethanolamine 141-43-5	X	X	X

16. OTHER INFORMATION

NFPA	**Health Hazards**	**Flammability**	**Instability**	**Special Hazards**
	Not determined	Not determined	Not determined	Not determined
HMIS	**Health Hazards**	**Flammability**	**Physical Hazards**	**Personal Protection**
	0	0	0	0

Issue Date 09-Mar-2012
Revision Date: 18-Sep-2015
Revision Note Format Update

SDS DATE: 11/11/2015___

SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: McKesson Triple Antibiotic ointment

MFR #: 118-42213

DISTRIBUTED BY:

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

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

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

PRODUCT DESCRIPTION: First aid antibiotic

SECTION 2: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: Topical

POTENTIAL HEALTH EFFECTS: This is a pharmaceutical material available without a prescription- use only as directed. See product packaging for further information concerning adverse effects and drug interaction precautions.

EYES: May cause irritation with symptoms of reddening, tearing and stinging.

SKIN: Allergy to any ingredient may cause anaphylactic shock.

INGESTION: Symptoms of ingestion may include abdominal pain, nausea, vomiting, and diarrhea.

INHALATION: Not applicable.

ACUTE HEALTH HAZARDS: The chief health hazard associated with exposure during normal use and handling is the potential for irritation of contaminated skin. Individuals who have had allergic reactions to products containing Aminoglycosides or any other components of this product may experience allergic reactions to this product. Allergic reactions may be severe and can be life-threatening in certain individuals.

CHRONIC HEALTH HAZARDS: Stop use and ask a doctor if condition worsens symptoms persist more than 7 days or clear up and occur again in a few days.

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: Pre-existing skin conditions may be aggravated by repeated overexposures to this product.

CARCINOGENICITY

OSHA:	Not listed	**ACGIH:**	Not listed	**NTP:**	Not listed	**IARC:**	Not listed

OTHER: N/A

SECTION 2 NOTES: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to the manufacturer's directions.

SDS DATE: 11/11/2015

SECTION 3: COMPOSITION/ INFORMATION OF INGREDIENTS

INGREDIENT	CAS NO.	%	Exposure Limits
Petrolatum	8009-03-8	10-100	
Neomycin sulfate	1405-10-3	0.1-1	
Polymyxin B sulfate	1405-20-5	0.01-0.1	
Bacitracin zinc	1405-89-6	0.1-1	

SECTION 3 NOTES: The formulations for these products are proprietary information. Inactive ingredients of less than 1% not displayed above.

SECTION 4: FIRST-AID MEASURES

EYES: In case of contact, flush with copious amounts of water for at least 15 minutes. Call a physician.

SKIN: If adverse skin effects occur, discontinue use. Seek medical attention.

INGESTION: In case of accidental ingestion, contact your regional poison center or physician immediately.

INHALATION: Not applicable.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure.

SECTION 4 NOTES: Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of label and SDS to physician or health professional with the contaminated individual.

SECTION 5: FIRE-FIGHTING MEASURES

FLAMMABLE LIMITS IN AIR, UPPER: Not Established
(% BY VOLUME) LOWER: Not Established

FLASH POINT: Not Established
METHOD USED: N/A

AUTOIGNITION TEMPERATURE: Not Established

NFPA HAZARD CLASSIFICATION

HEALTH:	2	FLAMMABILITY:	1	REACTIVITY:	0	OTHER:	N/A

HMIS HAZARD CLASSIFICATION

HEALTH:	2	FLAMMABILITY:	1	REACTIVITY:	N/A	PERSONAL:	0

EXTINGUISHING MEDIA: Water Fog, Sand, Earth, Dry Chemical, Foam

SPECIAL FIRE FIGHTING PROCEDURES: Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

UNUSUAL FIRE AND EXPLOSION HAZARDS: None known.

HAZARDOUS DECOMPOSITION PRODUCTS: None known.

SECTION 5 NOTES: See section 9 for physical and chemical properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: Use appropriate personal protective equipment during clean up. Scrape or shovel material. Use oil absorbent rags.
SECTION 6 NOTES: See Sections 9 and 10 for additional physical, chemical and hazard information.

SECTION 7: HANDLING AND STORAGE

HANDLING: Keep this and all drugs out of the reach of children. Avoid contact with eyes.

STORAGE: Store in a dry place away from excessive heat, in original or similar waterproof containers. Use normal precautions for storage of a drug.
OTHER PRECAUTIONS: Follow SPECIFIC USE INSTRUCTIONS supplied with this product.

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

VENTILATION: None Required.

RESPIRATORY PROTECTION: None Required.

EYE PROTECTION: Eye protection, as necessary to prevent excessive contact.

SKIN PROTECTION: None required when used as intended.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

WORK HYGIENIC PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product.

EXPOSURE GUIDELINES: Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of label and SDS to physician or health professional with the contaminated individual.

SECTION 8 NOTES: This guidance applies to the handling of the active ingredient(s) in this formulation. The end-user should perform an appropriate risk assessment when handling other forms or formulations of this active ingredient.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: yellow to off-white, nearly odorless

PHYSICAL STATE: ointment

pH AS SUPPLIED: N/A
pH (Other): N/A
BOILING POINT: Not Established
MELTING POINT: Not Established
FREEZING POINT: Not Established
VAPOR PRESSURE (mmHg): Not Established
DENSITY (lb/gal): Not Established
SPECIFIC GRAVITY (H2O = 1): 0.8
EVAPORATION RATE: Not Established
BASIS (=1): N/A
SOLUBILITY IN WATER: Not soluble
PERCENT SOLIDS BY WEIGHT: Not Established
PERCENT VOLATILE: Not Established
BY WT/ N/A **BY VOL @** N/A
VOLATILE ORGANIC COMPOUNDS (VOC): Not Established
WITH WATER: N/A **LBS/GAL**
WITHOUT WATER: N/A **LBS/GAL**
MOLECULAR WEIGHT: Not Established
VISCOSITY: Not Established

SECTION 9 NOTES: See Section 5 for flammability/explosivity information.

McKESSON

SDS DATE: 11/11/2015

SECTION 10: STABILITY AND REACTIVITY

	STABLE	UNSTABLE
STABILITY:	X	

CONDITIONS TO AVOID (STABILITY): Avoid excessive heat and light

INCOMPATIBILITY (MATERIAL TO AVOID): Oxidizing agents

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: Carbon oxides, nitrogen oxides, and sulfur oxides.

HAZARDOUS POLYMERIZATION: Will not occur

CONDITIONS TO AVOID (POLYMERIZATION): N/A

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: No data available for this product.

SECTION 11 NOTES: This information pertains to the formulated product unless indicated otherwise.

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: This product has not been tested for Eco toxicity.
SECTION 12 NOTES: There is no environmental data available for this product.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incarceration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: Disposal must be in accordance with federal, state/provincial, and/or local regulations.

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION
- **PROPER SHIPPING NAME:** N/A
- **HAZARD CLASS:** N/A
- **DOT SHIPPING ID NUMBER:** N/A
- **DOT PACKING GROUP:** N/A
- **DOT HAZARD CLASS:** N/A
- **DOT LABEL STATEMENT:** N/A

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

AIR TRANSPORTATION
- **PROPER SHIPPING NAME:** N/A
- **HAZARD CLASS:** N/A
- **ID NUMBER:** N/A

PACKING GROUP: N/A
LABEL STATEMENTS: N/A

SECTION 14 NOTES: This material is not subject to the transportation regulations of DOT, IATA, and the ADR.

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TSCA (TOXIC SUBSTANCE CONTROL ACT): Exempt

CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): Not listed

SARA 311/312 HAZARD CATEGORIES: N/A

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

STATE REGULATIONS: When used internally, the Neomycin Sulfate component of this product is on the California Proposition 65 lists as a compound that is known to cause developmental harm.

INTERNATIONAL REGULATIONS: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

SECTION 15 NOTES: For details on your regulatory requirements you should contact the appropriate agency in your state.

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A

PREPARATION INFORMATION:
SDS CREATION DATE: November 11, 2015
SDS VERSION: Original

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

SAFETY DATA SHEET

1. Identification

Product identifier **MENVEO VACCINE COMPONENT 1 OF 2**

Other means of identification

Synonyms MENINGOCOCCAL CONJUGATE VACCINE, FORMULATED PRODUCT

Recommended use Medicinal Product.

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

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249

Email Address: msds@gsk.com
Website: www.gsk.com

EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES:
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

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

Label elements

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

Hazard(s) not otherwise classified (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	%
MENINGOCOCCAL A OLIGOSACCHARIDE AND DIPTHERIAE PROTEIN CONJUGATE			100

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

4. First-aid measures

Inhalation Move to fresh air. 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	Not established.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Use care in handling/storage.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Storage temperature: between 2C and 8C. Do not allow material to freeze. Dispose of properly if frozen.

8. Exposure controls/personal protection

Occupational exposure limits

GSK
Not established

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	
Appropriate engineering controls	General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
Other	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
Respiratory protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.

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

9. Physical and chemical properties

Appearance	
Physical state	Solid.
Form	Powder.
Color	White/off-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 available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Do not freeze.
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	Not established.

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. 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	Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

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 likely, due to the form of the product.
Further information	Caution - Pharmaceutical agent. 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.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Mobility in general	Not available.
Other adverse effects	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)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

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

Not regulated.

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

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

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

Not listed.

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

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

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

International Inventories

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

Country(s) or region	Inventory name	On inventory (yes/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 06-19-2015

Version # 01

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

HMIS® ratings
Health: 0
Flammability: 1
Physical hazard: 0

NFPA ratings
Health: 0
Flammability: 1
Instability: 0

References GSK Hazard Determination

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

RICHMOND OXYGEN
RichmondOxygen.com

Safety Data Sheet
Oxygen, Compressed

SDS# 10001

Section 1: Product and Company Information

Richmond Oxygen
11009 Richardson Road
Ashland VA 23005

Phone: (804) 798-4243
Fax: (804) 798-2549

Emergency contact: 1-800-535-5053

Product code: Oxygen, Compressed
Part No. SDS# 10001

Section 2: Hazards Identification

DANGER

Hazard Classification:
Gases Under Pressure
Oxidizing Gas (Category 1)

Hazard Statements:
Contains gas under pressure; may explode if heated
May cause or intensify fire; oxidizer

Precautionary Statements

Prevention:
Keep reduction valves/valves and fittings free from oil and grease.
Keep and store away from clothing and combustible materials.

Response:
In case of fire: Stop leak if safe to do so.

Storage:
Protect from sunlight.
Store in well-ventilated place.

SDS# 10001

Section 3: Composition/Information on Ingredients

CAS #
7782-44-7

Chemical Substance	Chemical Family	Trade Names
OXYGEN, COMPRESSED GAS	Inorganic, gas	OXYGEN; DIOXYGEN; MOLECULAR OXYGEN; OXYGEN MOLECULE; PURE OXYGEN; UN 1072; O2

Section 4: First Aid Measures

Skin Contact	Eye Contact	Ingestion	Inhalation	Note to Physicians
None expected	None expected	Not likely route of exposure	If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.	None

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Products of Combustion	Protection of Firefighters
Non-flammable. Use extinguishing agent appropriate for the material which is burning. Use water in large quantities for fires involving oxygen.	Oxides of burning material	• Respiratory protection may be needed for frequent or heavy exposure. • None

Section 6: Accidental Release Measures

Personal Precautions	Environmental Precautions	Methods for Containment
Keep unnecessary people away, isolate hazard area and deny entry. Ventilate closed spaces before entering.	Avoid contact with combustible materials.	Stop leak if possible without personal risk.

Methods for Cleanup	Other Information
Stop leak and ventilate	None

Section 7: Handling and Storage

Handling	Storage
Store and handle in accordance with all current regulations and standards. Subject to storage regulations: U.S. OSHA 29 CFR 1910.101.	Keep separated from incompatible substances.

Section 8: Exposure Controls/Personal Protection

Exposure Guidelines
OXYGEN, COMPRESSED GAS: No occupational exposure limits established.

Engineering Controls

Handle only in fully enclosed systems.

Eye Protection	Skin Protection	Respiratory Protection
Eye protection not required, but recommended.	Protective clothing is not required.	Respiratory protection may be needed for frequent or heavy exposure.

General Hygiene considerations

- Avoid breathing vapor or mist
- Avoid contact with eyes and skin
- Wash thoroughly after handling and before eating or drinking

Section 9: Physical and Chemical Properties

Physical State	Appearance	Color	Change in Appearance	Physical Form	Odor	Taste
Gas	Clear	Colorless	N/A	Gas	Odorless	Tasteless

Flash Point	Flammability	Partition Coefficient	Autoignition Temperature	Upper Explosive Limits	Lower Explosive Limits
Not flammable	Not Available	Not Available	Nonflammable	Nonflammable	Nonflammable

Boiling Point	Freezing Point	Vapor Pressure	Vapor Density	Specific Gravity	Water Solubility	pH	Odor Threshold	Evaporation Rate	Viscosity
-297 F (-183 C)	-360 F (-218 C)	760 mmHg @ -183 C	1.1 (Air=1)	N/A	3.2% @ 25 C	N/A	Not available	N/A	0.02075 cP @ 25 C

Molecular Weight	Molecular Formula	Density	Weight per Gallon	Volatility by Volume	Volatility	Solvent Solubility
31.9988	O2	1.309 g/L @ 25 C	Not available	N/A	N/A	Soluble: Alcohol

Section 10: Stability and Reactivity

Stability	Conditions to Avoid	Incompatible Materials
Stable at normal temperatures and pressure.	Stable at normal temperatures and pressure.	Combustible materials, halo carbons, metals, bases, reducing agents, amines, metal salts, oxidizing materials, alkaline earth and alkali metals

Hazardous Decomposition Products	Possibility of Hazardous Reactions
Miscellaneous decomposition products	Will not polymerize.

Section 11: Toxicology Information

Acute Effects

Oral LD50	Dermal LD50	Inhalation
Not established	Not established	Irritation, changes in body temperature, nausea, difficulty breathing, irregular heartbeat, dizziness, disorientation, hallucinations, mood swings, pain in extremities, tremors, lung congestion, convulsions

Eye Irritation	Skin Irritation	Sensitization
No information on significant adverse effects	No information on significant adverse effects	No significant target effects reported.

Chronic Effects

Carcinogenicity	Mutagenicity	Reproductive Effects	Developmental Effects
Not known	Available	Available	No Data

Section 12: Ecological Information

Fate and Transport

Eco toxicity	Persistence / Degradability	Bioaccumulation / Accumulation	Mobility in Environment
Fish toxicity: Not available Invertibrate toxicity: Not available Algal toxicity: Not available Phyto toxicity: Not available Other toxicity: Not available	Not available	Low bioaccumulation	Not available

Section 13: Disposal Considerations

Dispose in accordance with all applicable regulations. Subject to disposal regulations: U.S. EPA 40 CFR 262. Hazardous Waste Number(s): D001.

Section 14: Transportation Information

U.S. DOT 49 CFR 172.101

Proper Shipping Name	ID Number	Hazard Class or Division	Packing Group	Labeling Requirements	Passenger Aircraft or Railcar Quantity Limitations	Cargo Aircraft Only Quantity Limitations	Additional Shipping Description
Oxygen, compressed	UN1072	2.2	Not available	2.2; 5.1	75 kg or L	150 kg	N/A

Canadian Transportation of Dangerous Goods

Shipping Name	UN Number	Class	Packing Group / Risk Group
Oxygen, compressed	UN1072	2.2; 5.1	Not applicable

Section 15: Regulatory Information

U.S. Regulations

CERCLA Sections	SARA 355.30	SARA 355.40
Not regulated	Not regulated	Not regulated

SARA 370.21

Acute	Chronic	Fire	Reactive	Sudden Release
No	No	Yes	No	Yes

SARA 372.65

Not regulated

OSHA Process Safety

Not regulated

State Regulations

CA Proposition 65
Not regulated

Canadian Regulations

WHMIS Classification
A,C

National Inventory Status

US Inventory (TSCA)	TSCA 12b Export Notification	Canada Inventory (DSL/NDSL)
Listed on inventory.	Not listed	Not determined.

Section 16: Other Information

NFPA Rating
HEALTH=0 FIRE=0 REACTIVITY=0

0 = minimal hazard, 1 = slight hazard, 2 = moderate hazard, 3 = severe hazard, 4 = extreme hazard

RICHMOND OXYGEN
RichmondOxygen.com

Safety Data Sheet
Oxygen, Compressed

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Emergency contact: 1-800-535-5053

Product code: Oxygen, Compressed
Part No. SDS# 10001

Section 2: Hazards Identification

DANGER

Hazard Classification:
Gases Under Pressure
Oxidizing Gas (Category 1)

Hazard Statements:
Contains gas under pressure; may explode if heated
May cause or intensify fire; oxidizer

Precautionary Statements

Prevention:
Keep reduction valves/valves and fittings free from oil and grease.
Keep and store away from clothing and combustible materials.

Response:
In case of fire: Stop leak if safe to do so.

Storage:
Protect from sunlight.
Store in well-ventilated place.

SDS# 10001

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CAS #
7782-44-7

Chemical Substance	Chemical Family	Trade Names
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Suitable Extinguishing Media	Products of Combustion	Protection of Firefighters
Non-flammable. Use extinguishing agent appropriate for the material which is burning. Use water in large quantities for fires involving oxygen.	Oxides of burning material	• Respiratory protection may be needed for frequent or heavy exposure. • None

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Personal Precautions	Environmental Precautions	Methods for Containment
Keep unnecessary people away, isolate hazard area and deny entry. Ventilate closed spaces before entering.	Avoid contact with combustible materials.	Stop leak if possible without personal risk.

Methods for Cleanup	Other Information
Stop leak and ventilate	None

Section 7: Handling and Storage

Handling	Storage
Store and handle in accordance with all current regulations and standards. Subject to storage regulations: U.S. OSHA 29 CFR 1910.101.	Keep separated from incompatible substances.

Section 8: Exposure Controls/Personal Protection

Exposure Guidelines
OXYGEN, COMPRESSED GAS: No occupational exposure limits established.

Engineering Controls

Handle only in fully enclosed systems.

Eye Protection	Skin Protection	Respiratory Protection
Eye protection not required, but recommended.	Protective clothing is not required.	Respiratory protection may be needed for frequent or heavy exposure.

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- Avoid breathing vapor or mist
- Avoid contact with eyes and skin
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Physical State	Appearance	Color	Change in Appearance	Physical Form	Odor	Taste
Gas	Clear	Colorless	N/A	Gas	Odorless	Tasteless

Flash Point	Flammability	Partition Coefficient	Autoignition Temperature	Upper Explosive Limits	Lower Explosive Limits
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Hazardous Decomposition Products	Possibility of Hazardous Reactions
Miscellaneous decomposition products	Will not polymerize.

Section 11: Toxicology Information

Acute Effects

Oral LD50	Dermal LD50	Inhalation
Not established	Not established	Irritation, changes in body temperature, nausea, difficulty breathing, irregular heartbeat, dizziness, disorientation, hallucinations, mood swings, pain in extremities, tremors, lung congestion, convulsions

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No information on significant adverse effects	No information on significant adverse effects	No significant target effects reported.

Chronic Effects

Carcinogenicity	Mutagenicity	Reproductive Effects	Developmental Effects
Not known	Available	Available	No Data

Section 12: Ecological Information

Fate and Transport

Eco toxicity	Persistence / Degradability	Bioaccumulation / Accumulation	Mobility in Environment
Fish toxicity: Not available Invertibrate toxicity: Not available Algal toxicity: Not available Phyto toxicity: Not available Other toxicity: Not available	Not available	Low bioaccumulation	Not available

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U.S. DOT 49 CFR 172.101

Proper Shipping Name	ID Number	Hazard Class or Division	Packing Group	Labeling Requirements	Passenger Aircraft or Railcar Quantity Limitations	Cargo Aircraft Only Quantity Limitations	Additional Shipping Description
Oxygen, compressed	UN1072	2.2	Not available	2.2; 5.1	75 kg or L	150 kg	N/A

Canadian Transportation of Dangerous Goods

Shipping Name	UN Number	Class	Packing Group / Risk Group
Oxygen, compressed	UN1072	2.2; 5.1	Not applicable

Section 15: Regulatory Information

U.S. Regulations

CERCLA Sections	SARA 355.30	SARA 355.40
Not regulated	Not regulated	Not regulated

SARA 370.21

Acute	Chronic	Fire	Reactive	Sudden Release
No	No	Yes	No	Yes

SARA 372.65

Not regulated

OSHA Process Safety

Not regulated

State Regulations

CA Proposition 65
Not regulated

Canadian Regulations

WHMIS Classification
A,C

National Inventory Status

US Inventory (TSCA)	TSCA 12b Export Notification	Canada Inventory (DSL/NDSL)
Listed on inventory.	Not listed	Not determined.

Section 16: Other Information

NFPA Rating
HEALTH=0 FIRE=0 REACTIVITY=0

0 = minimal hazard, 1 = slight hazard, 2 = moderate hazard, 3 = severe hazard, 4 = extreme hazard

sanofi pasteur
The vaccines division of sanofi-aventis Group

Material Safety Data Sheet for Sanofi Pasteur Vaccines and Biologics

Contact: Customer Service – 1-800-822-2463 **Effective Date: February 3, 2011**

NFPA Rating (0,0,0)

Product:

ActHIB®, Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)

ADACEL®, Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed

DAPTACEL®, Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

DECAVAC®, Tetanus and Diphtheria Toxoids Adsorbed (For 7 years of age and older)

DT, Diphtheria and Tetanus Toxoids Adsorbed USP (For Pediatric Use up to 7 years of age)

Fluzone®, Influenza Virus Vaccine (All presentations)

Imogam® Rabies-HT, Rabies Immune Globulin (Human) USP Heat Treated

IMOVAX® RABIES, Rabies Vaccine

IPOL®, Poliovirus Vaccine Inactivated

Menactra®, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine

Menomune®-A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined

Pentacel®, Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine

Tetanus Toxoid Adsorbed

TheraCys®, BCG Live (Intravesical)

Tripedia®, Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

sanofi pasteur . Discovery Drive . Swiftwater, Pennsylvania 18370 . Tel.: 1-800-VACCINE (1-800-822-2463) . www.sanofipasteur.us
Sanofi Pasteur Inc.

Tubersol®, Tuberculin Purified Protein Derivative (Mantoux)

Typhim Vi®, Typhoid Vi Polysaccharide Vaccine

YF-VAX®, Yellow Fever Vaccine

Diluent:

Diluent for reconstitution of ActHIB vaccine

Diluent for reconstitution of IMOVAX RABIES vaccine

Diluent for reconstitution of Menomune vaccine

Diluent for reconstitution of TheraCys BCG

Diluent for reconstitution of YF-VAX vaccine

We have conducted a hazard evaluation of the constituents of the above products in accordance with OSHA's Hazard Communication Standard [29 CFR 1910.1200(d)]. It has been determined that the product or diluent ingredients do not pose a physical or health hazard at the percentages present in the mixtures based on the guidelines set by OSHA's Hazard Communication Standard. Therefore, as of this date, we are not required under OSHA Federal Regulations to distribute a Material Safety Data Sheet for these products.

For more information concerning product safety refer to the prescribing information or call Customer Service at the phone number listed above.

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 Inhalation (vapors)	13333.3 mg/kg 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: 11.11.15

*** SAFETY DATA SHEET***

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: SELECT® Povidone Iodine, USP Swabsticks
REORDER #: 986 (1's), 987 (3's)

MANUFACTURED FOR: McKesson Medical Surgical, Inc.
9954 Mayland Drive
Richmond, VA 23233
INFORMATION LINE: 1-800-777-4908

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

PRODUCT DESCRIPTION: N/A

SECTION 2: COMPOSITION/INFORMATION OF INGREDIENTS

INGREDIENT	CAS NO.	%	EXPOSURE LIMITS
Povidone Iodine Powder	25655-41-8	4.9%	N/A
Purified Water	7732-18-5	95.1%	N/A

SECTION 2 NOTES: N/A

SECTION 3: HAZARDS IDENTIFICATION

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

POTENTIAL HEALTH EFFECTS

EYES: Irritation to eyes if contact occurs

SKIN: Irritation to skin if contact occurs

INGESTION: Harmful if swallowed

INHALATION: Harmful if inhaled

ACUTE HEALTH HAZARDS: N/A

CHRONIC HEALTH HAZARDS: N/A

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: N/A

CARCINOGENICITY

OSHA: N/A **ACGIH:** N/A **NTP:** N/A **IARC:** N/A
OTHER: N/A

SECTION 3 NOTES: N/A

SECTION 4: FIRST-AID MEASURES

EYES: Immediately flood the eye with plenty of water for at least 15 minutes, holding the eyes open. Obtain medical attention if soreness or redness persists.

SKIN: Immediately flood the skin with large quantities of water. Remove contaminated clothing and continue washing. Obtain medical attention if blistering occurs or redness persists.

INGESTION: Do not induce vomiting. Have victim drink 1—3 glasses of water to dilute stomach contents. If there is difficulty in breathing, give oxygen. Obtain medical attention immediately.

INHALATION: Remove from exposure. If there is difficulty in breathing, give oxygen. Obtain medical attention immediately.

McKESSON

SDS DATE: 11.11.15

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: N/A

SECTION 4 NOTES: N/A

SECTION 5: FIRE-FIGHTING MEASURES

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

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

AUTOIGNITION TEMPERATURE: N/A

NFPA HAZARD CLASSIFICATION
HEALTH: N/A **FLAMMABILITY:** N/A **REACTIVITY:** N/A
OTHER: N/A

HMIS HAZARD CLASSIFICATION
HEALTH: N/A **FLAMMABILITY:** N/A **REACTIVITY:** N/A
PROTECTION: N/A

EXTINGUISHING MEDIA: Use dry chemical, foam or carbon dioxide. Be aware of the possibility of re-ignition. Keep containers and surrounding cool with water spray.

SPECIAL FIRE FIGHTING PROCEDURES: Wear full protective clothing and self-contained breathing apparatus.

UNUSUAL FIRE AND EXPLOSION HAZARDS: N/A

HAZARDOUS DECOMPOSITION PRODUCTS: N/A

SECTION 5 NOTES: Non-flammable liquid.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: N/A

SECTION 6 NOTES: N/A

SECTION 7: HANDLING AND STORAGE

HANDLING: N/A

STORAGE: Store in the sealed containers. Storage areas should be cool, dry, and well-ventilated away from incompatible materials.

OTHER PRECAUTIONS: N/A

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

VENTILATION: N/A

RESPIRATORY PROTECTION: N/A

EYE PROTECTION: N/A

SKIN PROTECTION: N/A

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

MCKESSON

SDS DATE: 11.11.15

WORK HYGIENIC PRACTICES: N/A

EXPOSURE GUIDELINES: N/A

SECTION 8 NOTES: N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: N/A

PHYSICAL STATE: N/A

pH AS SUPPLIED: N/A
pH (Other: N/A
BOILING POINT: N/A
MELTING POINT: N/A
FREEZING POINT: N/A
VAPOR PRESSURE (mmHg): N/A
@ N/A
VAPOR DENSITY (AIR = 1): N/A
@ N/A
SPECIFIC GRAVITY (H2O = 1): N/A
@ N/A
EVAPORATION RATE: N/A

BASIS (=1): N/A

SOLUBILITY IN WATER: N/A

PERCENT SOLIDS BY WEIGHT: N/A

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

VOLATILE ORGANIC COMPOUNDS (VOC): N/A

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

MOLECULAR WEIGHT: N/A
VISCOSITY: N/A
@ N/A

SECTION 9 NOTES: N/A

SECTION 10: STABILITY AND REACTIVITY

	STABLE	UNSTABLE
STABILITY:	**X**	

CONDITIONS TO AVOID (STABILITY): N/A

INCOMPATIBILITY (MATERIAL TO AVOID): N/A

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: N/A

HAZARDOUS POLYMERIZATION: N/A

CONDITIONS TO AVOID (POLYMERIZATION): N/A

McKESSON

SDS DATE: 11.11.15

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: N/A

SECTION 11 NOTES: N/A

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: N/A

SECTION 12 NOTES: N/A

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD:

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

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

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

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

SECTION 14 NOTES: N/A

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS
TSCA (TOXIC SUBSTANCE CONTROL ACT): N/A

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

311/312 HAZARD CATEGORIES: N/A

313 REPORTABLE INGREDIENTS: N/A

STATE REGULATIONS: N/A

INTERNATIONAL REGULATIONS: N/A

McKESSON

SDS DATE: 11.11.15

SECTION 15 NOTES: N/A

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A

PREPARATION INFORMATION: N/A

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

SAFETY DATA SHEET

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

Amneal Pharmaceuticals Pvt. Ltd.

Material Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

Product Information

Product name	Triamcinolone Acetonide Injection (10 or 40 mg/ml)
Version	0.0, 03/15/2016
Jurisdiction	This Material Safety Data Sheet was prepared for the jurisdiction USA.
Active substance	Triamcinolone Acetonide
Synonyms	Sterile Triamcinolone Acetonide Suspension USP; Kenalog-10 Injection; Kenalog-40 Injection
Product 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	Amneal Pharmaceuticals Pvt. Ltd. New Jersey United States of America
Emergency Phone Number	1-800- - ------ For all international transportation emergencies call Collect calls accepted.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Components	Concentration	CAS-No.
Hazardous components		
Triamcinolone Acetonide	1 - 4 %	76-25-5
Other ingredients		
Water	90 - 100 %	7732-18-5
Sodium Carboxymethylcellulose	<1 %	9004-32-4
Tween 80	<1 %	9005-65-6
Benzyl alcohol	<1 %	100-51-6
Hydrochloric acid	<1 %	7647-01-0
Sodium Chloride	<1 %	7647-14-5
Sodium Hydroxide	<1 %	1310-73-2

3. HAZARDS IDENTIFICATION

Emergency Overview

Appearance	liquid : white to off-white, suspension
Signal Word	Warning!
Hazard Statements	Teratogen May be harmful to fetus. Reproductive toxicant Target Organs: adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs, (embryo/fetus).

Continued

3. HAZARDS IDENTIFICATION	
Precautionary Measures	Avoid ingestion, inhalation, skin and eye contact. Wash hands after handling to minimize exposure. Wear suitable protective clothing and gloves. Pregnant or nursing women should avoid exposure. Prevent release to the environment.
Potential Health Effects	
Eyes	Possible mild eye irritant
Skin	Rapidly absorbed through skin., Repeated exposure may cause skin dryness or cracking., May be harmful if absorbed through skin.
Ingestion	May cause damage to organs through prolonged or repeated exposure if swallowed.
Inhalation	May cause damage to organs through prolonged or repeated exposure if inhaled.
Target Organs	adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs, (embryo/fetus)
Signs and Symptoms	Chronic: 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, vomiting, anorexia, gastrointestinal disturbance, sore throat, dry mouth, taste disturbance, speech difficulty, congestion, redness and swelling of eyes, vision changes, facial swelling, skin thinning, acne, redness and swelling of skin, hives, bruising, superficial burning sensation, tingling.
Medical conditions aggravated include:	diabetes, Liver disorders, infection, immunodeficiency, hypertension, myasthenia gravis, osteoporosis, peptic ulcer, psychotic disorders, colitis, kidney disorders
Environmental Effects	Refer to Section 12

4. FIRST AID MEASURES	
Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention. Wash contaminated clothing before re-use.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Obtain medical attention.
Ingestion	Do NOT induce vomiting. Consult a physician if necessary. Never give anything by mouth to an unconscious person.

Continued

4. FIRST AID MEASURES	
Notes to physician	This material is a finished drug product for patient use. This material is used to provide relief of inflammatory and pruritic skin conditions. This product may cause: 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, vomiting, anorexia, gastrointestinal disturbance, sore throat, dry mouth, taste disturbance, speech difficulty, congestion, redness and swelling of eyes, vision changes, facial swelling, 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, sperm abnormalities, cataracts, glaucoma, nose changes, otitis, peptic ulcer, psychotic disorders, pancreatitis, changes in white blood cell parameters. Organs effected may include: adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs, (embryo/fetus). 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), drug 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. Pregnant or nursing women should avoid exposure.
Medical Surveillance	A pre-placement physical examination and history for employees with potential exposure to this compound is recommended. Baseline testing would include: Pre-placement:, blood glucose test, a complete blood count with differential. 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: Teratogen skin absorption hazard Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: carbon oxides, hydrogen halides
Other information:	Decontaminate protective clothing and equipment before reuse. Heating can release hazardous gases. HCl gas can form flammable or explosive mixtures with alcohols or metals.

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, disposable lab coat of low permeability with cuffs, double gloves and shoe covers. 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.

Continued

6. ACCIDENTAL RELEASE MEASURES	
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 spill area with a deactivating solution (if available) followed by detergent and water after spill pick-up. 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	Highly potent material. Avoid exposure - obtain special instructions before use. Avoid inhalation of vapour or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Storage Conditions	Store at room temperature. (20 - 25°C) Protect against light. Avoid freezing.
Container Requirements	Store in sturdy containers appropriate to maintain the integrity of this material for its intended use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit(s)	Company Guideline	ACGIH	OSHA	NIOSH
Triamcinolone Acetonide	1 µg/m3 (Skin), Developmental Toxicity	--	--	--
Benzyl alcohol	--	--	--	--
Sodium Hydroxide	--	2 mg/m3 Ceiling	2 mg/m3 TWA	2 mg/m3 Ceiling 10 mg/m3 IDLH
Hydrochloric acid	--	2 ppm Ceiling	5 ppm Ceiling 7 mg/m3 Ceiling	5 ppm Ceiling 7 mg/m3 Ceiling 50 ppm IDLH

Exposure Control Band	Triamcinolone Acetonide ***4*** -- The established company exposure guideline falls within Exposure Control Band 4 (range 1 -20 µg/m3).
Bristol-Myers Squibb Exposure Guidelines Summary	Triamcinolone Acetonide Materials require particular care and handling. Adherence to this guideline should protect employees from experiencing the therapeutic and/or adverse effects of this drug.
Recommended Industrial Hygiene Monitoring Methods	Contact the Bristol-Myers Squibb AIHA accredited Industrial Hygiene Laboratory at 732-227-7368. See Section 4 "Notes to Physician" for information on medical surveillance.

Continued

8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
Engineering Controls and Ventilation	When handling small quantities in a clinical setting, good room ventilation is desirable. Specific engineering controls should not be needed. When handling larger quantities, such as in a manufacturing setting, ensure worker exposure is below the recommended exposure limit. If significant aerosol (mist) is generated, use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit.
Respiratory protection	Respiratory protection is not required for normal use of this material. If the occupational exposure limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. Note: May cause damage to organs through prolonged or repeated exposure if inhaled.
Eye protection	Chemical splash resistant goggles should be worn when potential for splash exists.
Hand protection	Impervious nitrile, rubber and latex gloves are recommended. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.
Skin and body protection	It is recommended that a laboratory coat be worn when handling product.
Hygiene	Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES	
Appearance	
Physical State	liquid
Color	white to off-white
Form	suspension
Descriptive properties	
Molecular Weight	Not available
Molecular formula	Not applicable
Bulk density	Not available
Evaporation rate	Not available
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
Odor	Not remarkable.
Odor Threshold	Not available
pH	5 - 7
pKa	Not available
Particle Size	Not available
Solubility, Water	soluble
Specific Gravity/ Relative density	1.015
Viscosity	similar to water
Thermal/Stability properties	
Autoignition temperature	Not available
Boiling Point	100 °C
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, LEL	Not available

Continued

9. PHYSICAL AND CHEMICAL PROPERTIES	
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
Incompatible products	Not available
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.: carbon oxides, 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 Possible mild eye irritant
Skin irritation	Triamcinolone Acetonide Repeated exposure may cause skin dryness or cracking. skin thinning
Respiratory Irritation	Triamcinolone Acetonide May cause irritation of respiratory tract.
Sensitisation	Triamcinolone Acetonide Not a dermal sensitizer Allergic contact dermatitis is quite rare but has been reported.
Acute Toxicity Study	**Acute Oral** Triamcinolone Acetonide Oral LD50(mouse): 5,000 mg/kg **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

Continued

11. TOXICOLOGICAL INFORMATION

Repeated dose toxicity	Triamcinolone Acetonide **Assessment Repeat Dose Toxicity** Several studies were conducted. Results from these studies in multiple species were generally similar with respect to target organs and effects. See Section 11 Target Organs and Symptoms for a description of effects.
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.
Carcinogenicity	Triamcinolone Acetonide 104 Weeks Oral rat study : [tumor organs: liver] positive 104 Weeks Oral rat study : NOAEL = 0.001 mg/kg No treatment-related tumors were observed. 104 Weeks Oral mouse study : NOAEL = 0.003 mg/kg No treatment-related tumors were observed. **Carcinogenicity Assessment** Several studies were conducted. The results were negative and positive. Not classifiable as to its carcinogenicity to humans.

Carcinogenicity	**ACGIH**	**OSHA**	**NTP**	**IARC**
Triamcinolone Acetonide	--	--	--	--

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.
Human experience	**Experiences with Human Exposure** Triamcinolone Acetonide General effects therapeutic use - Symptoms: 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, vomiting, anorexia, gastrointestinal disturbance, sore throat, dry mouth, taste disturbance, speech difficulty,

Continued

11. TOXICOLOGICAL INFORMATION	
	congestion, redness and swelling of eyes, vision changes, facial swelling, skin thinning, acne, redness and swelling of skin, hives, bruising, superficial burning sensation, tingling. Other effects include: increase in blood pressure, Cushing's syndrome, electrolyte disturbance, hyperglycemia, adrenocortical insufficiency, withdrawal symptoms, osteoporosis, bone effects, menstrual irregularities, cataracts, glaucoma, nose changes, otitis, peptic ulcer, psychotic disorders, pancreatitis, changes in white blood cell parameters. **Epidemiology** Triamcinolone Acetonide Epidemiological study - Several studies have associated the development of oral clefts with exposure during pregnancy. Fetal effects include: decreased body weight .
Target Organs	Triamcinolone Acetonide adrenal glands, bone, muscle, gastrointestinal tract, immune system, eyes, nervous system, skin, female reproductive organs
Symptoms	Triamcinolone Acetonide See "Human Experience".
Other Toxicity Information	Not available
Other Information:	This MSDS may contain toxicological and/or pharmacological information derived from either the specified product or from compounds in the same pharmacological class.

12. ECOLOGICAL INFORMATION
Ecotoxicological Information (Aquatic) **Acute Toxicity to Aquatic Invertebrates** Triamcinolone Acetonide EC50 (Daphnia magna, 48 H) : > 100 mg/l
Ecotoxicological Information (Terrestrial) Not available
Chemical fate information **Biodegradation** Triamcinolone Acetonide Ultimate aerobic biodegradation (28 D) : 3 % ; Not Readily Biodegradable - unlikely to undergo rapid biodegradation in the environment
Summary Statements **Aquatic toxicity** Experimental data indicate low potential for acute harm to aquatic invertebrates **Chemical Fate** Not readily biodegradable.

Continued

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.

15. REGULATORY INFORMATION	
United States of America	
OSHA Hazard Classification	Teratogen, Target Organs.
313 Toxic Release Inventory. Listed Chemicals/Compounds	No components listed on the SARA 313 inventory.
TSCA Inventory	Not listed. Food, drug and cosmetic products are exempt from TSCA.
International	
Canada	
WHMIS	This product is not regulated under the Hazardous Products Act and Controlled Products Regulations. This product, however, may have significant health hazard and could meet the criteria for: D2A Very Toxic Material Causing Other Toxic Effects
DSL/NDSL	yes
Mexico	
Mexico Classification	Health classification - Serious Hazard - 3 - Substances that can cause serious or permanent harm under emergency conditions
Europe	
EINECS/ELINCS Number	Triamcinolone Acetonide: 200-948-7 Water: 231-791-2 Benzyl alcohol: 202-859-9 Sodium Chloride: 231-598-3 Sodium Hydroxide: 215-185-5 Hydrochloric acid: 231-595-7
R-phrase(s)	Medicinal products are exempt from classification and labeling requirements under EU Preparations Directive 1999/45/EC.

16. OTHER INFORMATION	
MSDS preparation information	
Prepared by	Corporate Quality, Environmental Health & Safety 1-732-227-7380
Prepared on	02/15/2016
	This Safety Data Sheet has been revised. This MSDS has been reformatted in a new electronic system. This data sheet contains changes from the previous version in section(s): All.

Continued

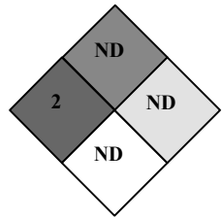
Other information

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



The information contained in this MSDS 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.

End of Safety Data Sheet

SANOFI PASTEUR

US - OSHA SAFETY DATA SHEET

Issue Date 24-Apr-2015 **Revision Date** 26-Oct-2017 **Version** 2

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

Product identifier

Product Name TUBERSOL®

Other means of identification

Product Information 10-test vial, 1 mL (NDC 49281-752-78); package of 1 vial, (NDC 49281-752-21)
50-test vial, 5 mL (NDC 49281-752-98); package of 1 vial, (NDC 49281-752-22)

Synonyms Tuberculin Purified Protein Derivative (Mantoux)

Recommended use of the chemical and restrictions on use

Recommended Use Aid diagnosis of tuberculosis infection (TB) in persons at increased risk of developing active disease.

Uses advised against Not available.

Details of the supplier of the safety data sheet

Supplier Address
Sanofi Pasteur
1 Discovery Drive
Swiftwater, PA 18370

Emergency telephone number

Company Phone Number 1-800-VACCINE (1-800-822-2463)
24 Hour Emergency Phone Number 1-570-957-4400
Emergency Telephone 1-570-957-4400

2. HAZARDS IDENTIFICATION

Classification

Health Hazards
Not classified.

Physical hazards
Not classified.

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

Label elements

Emergency Overview

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

Appearance Clear colorless liquid **Physical state** Liquid **Odor** Not available.

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Tuberculin Purified Protein Derivative (Mantoux)

Chemical Name	CAS No.	Weight-%
Purified Protein derivative of Mycobacterium tuberculosis	N/A	N/A
Sterile isotonic phosphate buffered saline	N/A	q.s to 100

Note: Ingredients below reportable levels are not listed.

4. FIRST AID MEASURES

First aid measures

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

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

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

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

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

Most important symptoms and effects, both acute and delayed

Symptoms Induration at test site if test is positive for TB.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

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

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical

Not available.

Hazardous combustion products Not available.

Explosion data

Sensitivity to Mechanical Impact Not available.

Sensitivity to Static Discharge None known.

Protective equipment and precautions for firefighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Wear appropriate personal protective equipment (see Section 8).

Environmental precautions

Environmental precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

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

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

7. HANDLING AND STORAGE

Precautions for safe handling

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

Conditions for safe storage, including any incompatibilities

Storage Conditions Store at 2° to 8°C (35° to 46°F). Do not freeze. Protect from light.

Incompatible materials Not available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

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

Appropriate engineering controls

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

Individual protection measures, such as personal protective equipment

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 colorless liquid	**Odor**	Not available.
Color	Clear	**Odor threshold**	Not available.

Property	**Values**	**Remarks • Method**
pH	Not available.	
Melting point/freezing point	Not available.	
Boiling point / boiling range	Not available.	
Flash point	Not available.	

Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Flammability Limit in Air	
Upper flammability limit:	Not available.
Lower flammability limit:	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Specific Gravity	Not available.
Water solubility	Not available.
Solubility in other solvents	Not available.
Partition coefficient	Not available.
Autoignition temperature	Not available.
Decomposition temperature	Not available.
Kinematic viscosity	Not available.
Dynamic viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.

Other Information

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

10. STABILITY AND REACTIVITY

Reactivity
Not reactive under normal conditions.

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal handling.

Hazardous polymerization Hazardous polymerization does not occur.

Conditions to avoid
Not available.

Incompatible materials
Not available.

Hazardous Decomposition Products
None under normal use conditions.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information No data available.

Inhalation No impact known or expected under normal use.

Eye contact No impact known or expected under normal use.

Skin Contact No impact known or expected under normal use.

Ingestion No impact known or expected under normal use.

Information on toxicological effects

Symptoms Induration at test site if test is positive for TB.

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

Skin corrosion/irritation	Not available.
Serious eye damage/eye irritation	Not available.
Irritation	Not available.
Corrosivity	Not available.
Sensitization	Not available.
Germ cell mutagenicity	TUBERSOL has not been evaluated for its mutagenic potential.
Carcinogenicity	TUBERSOL has not been evaluated for its carcinogenic potential.
Reproductive toxicity	Pregnancy Category C: Animal reproduction studies have not been conducted with TUBERSOL. It is also not known whether TUBERSOL can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. It is not known whether TUBERSOL is excreted in human milk.
Developmental Toxicity	Not available.
Teratogenicity	Not available.
STOT - single exposure	Not classified.
STOT - repeated exposure	Not classified.
Chronic toxicity	Not available.
Subchronic toxicity	Not available.
Target Organ Effects	Not available.
Neurological effects	Not available.
Other adverse effects	Not available.
Aspiration hazard	Not available.

Numerical measures of toxicity - Product Information

12. ECOLOGICAL INFORMATION

Ecotoxicity

Not available.

Persistence and degradability

Not available.

Bioaccumulation

Not available.

Mobility

Not available.

Other adverse effects Not available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes	Disposal should be in accordance with applicable regional, national and local laws and regulations.
Contaminated packaging	Disposal should be in accordance with applicable regional, national and local laws and regulations.
US EPA Waste Number	Not applicable.
California Hazardous Waste Codes	Not applicable.

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
No component is on the Proposition 65 list.

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

16. OTHER INFORMATION

Prepared By	IES Engineers
Issue Date	24-Apr-2015
Revision Date	26-Oct-2017
Revision Note	Updated California Proposition 65 Information

Disclaimer

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

End of Safety Data Sheet

VAQTA®

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	VAQTA®
Other Names	
Manufacturer's Product Code	80600001 VAQTA Adult 1.0mL x 1 Syringe Hepatitis A Vaccine Inact 1.0mL VAQTA (Adult) Syringe 80600002 VAQTA (Adult) Vial Hepatitis A Vacc Inact 1.0mL
Use	Hepatitis A Vaccine
Manufacturer's Name	MERCK & CO., INC.
Address	One Merck Drive, Whitehouse Station, NJ 08889-0100 USA
Telephone	(908) 423-1000
Emergency Telephone	1-908-423-6000
Supplier's Name	Seqirus Pty. Ltd. (ABN 26 160 735 035)
Address	63 Poplar Road, Parkville, Victoria 3052, Australia
Telephone	+61 03 9389 1911
Emergency Telephone	+61 03 9389 1984 (24hr)

2. HAZARDS IDENTIFICATION

Not classified as hazardous according to the criteria of the 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:*
Hepatitis A protein	-	< 0.01 %
Other non-hazardous ingredients	-	Up to 100%

4. FIRST AID MEASURES

Eye In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. 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.

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 reuse.

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.

Advice to Doctor Treat supportively and symptomatically. For additional guidance refer to the current prescribing information or the local poison control centre.

5. FIRE FIGHTING MEASURES

Fire/Explosion Hazard None known

Fire Extinguishing Media In case of fire, use water spray (fog), foam, dry chemical, or CO_2.

Hazchem Code Not applicable

6. ACCIDENTAL RELEASE MEASURES

Minor Spills Contain spilled material. 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.

Major Spills Contain spilled material. 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.

7. HANDLING AND STORAGE

Avoid direct contact with skin and eyes. Wash thoroughly after handling.

Keep container tightly closed. Store vials at 2-8ºC.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards No exposure limits set by SWA or ACGIH.

Engineering Controls None required when handling sealed vials.
Adequate ventilation should be provided if there is risk of aerosol formation.

Personal Protection 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 - Additional body garments should be used based upon the task being performed (e.g., gloves, sleevelets, apron, gauntlets, disposable suits).

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance Slightly opaque white suspension

Odour Not available

pH Not available

Boiling Point/Melting Point Not available

Vapour Pressure Not available

Vapour Density Not available

Specific Gravity Not available

Flashpoint Not applicable

Flammability Limits Not applicable

Solubility in Water No available

10. STABILITY AND REACTIVITY

Reactivity Not available

Stability Not available

Decomposition Products Not known

11. TOXICOLOGICAL INFORMATION

Skin Non-irritating to the skin.

Eye Non-irritating to the eyes.

Inhalation Not available

Ingestion Not available

Chronic Health Effects This compound is a vaccine indicated for immunization against infection caused by hepatitis A virus. VAQTA has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility. In clinical trials, injection-site complaints were the most frequently reported complaints. Other side effects reported in clinical trials included fatigue, fever, stomach pain, throat inflammation, muscle pain, diarrhoea, vomiting, menstruation disorder, and headache. Not listed as a carcinogen by OSHA, NTP or IARC.

12. ECOLOGICAL INFORMATION

Not available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

UN Number Not applicable

Proper Shipping Name Not applicable

Transport Hazard Class Not applicable

Packing Group Not applicable

Hazchem Code Not applicable

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Date of Issue	20 March 2017
Reason for update	Update business details Update to GHS format
Abbreviations	
SWA	Safe Work Australia
WHS	Work, Health and Safety
GHS	Globally Harmonised System
ACGIH	American Conference of Governmental Industrial Hygienists
ADG Code	Australian Dangerous Goods Code
UN Number	United Nations Number
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

SAFETY DATA SHEET

Vaseline Petroleum Jelly – All Variants

Section 1. Identification

Product names	:	Vaseline Petroleum Jelly – All Variants Pure, Baby, Cocoa
Product type	:	Skin Protectant
UPC Code	:	305212335002, 305212326000, 305210069275
Internal product code	:	11001016, 11002034, 83142385

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

Identified uses
Industrial uses: Uses of substances as such or in preparations at industrial sites Consumer uses: Private households (= general public = consumers) Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

Supplier's details	:	UNILEVER 700 Sylvan Avenue Englewood Cliffs NJ 07632 USA
Emergency telephone number (with hours of operation)	:	Phone #: 800-761-3683 Monday thru Friday (8:30 AM – 5:00 PM EST) Emergency #: 800-745-9269 (24 hours) Poison Control #: 800-949-7866 (24 hours) CHEMTREC #: 800-424-9300 (24 hours, Transportation Emergencies)

Consumer Information:
For information regarding the use of this product by a consumer, please refer directly to the product label. This industrial MSDS is provided for workplace employees, per US OSHA regulations. It contains recommendations for handling of this product in an occupational, or workplace, setting.

Any first aid or warnings that are applicable to consumer use are stated directly on the product label, in accordance with all applicable government regulations.

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 MSDS contains valuable information critical to the safe handling and proper use of the product. This MSDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : No signal word.
Hazard statements : No known significant effects or critical hazards.

Precautionary statements

General : Keep out of reach of children.
Prevention : Not applicable.
Response : Not applicable.

Storage : Not applicable.
Disposal : Not applicable.
Supplemental label elements : None known.
Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

CAS number/other identifiers

Ingredient name	%	CAS number
Petrolatum	75 - 100	8009-03-8

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

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.
Occupational exposure limits, if available, are listed in Section 8.

Section 4. First-aid measures

Description of necessary first aid measures

Eye contact	:	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
Inhalation	:	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
Skin contact	:	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
Ingestion	:	Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

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

Over-exposure signs/symptoms

Eye contact	:	No specific data.
Inhalation	:	No specific data.
Skin contact	:	No specific data.
Ingestion	:	No specific data.

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

Notes to physician	:	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments	:	No specific treatment.
Protection of first-aiders	:	No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	:	Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	:	None known.
NFPA 30B Classification	:	Not available.
Specific hazards arising from the chemical	:	No specific fire or explosion hazard.

Hazardous thermal decomposition products	:	No specific data.
Special protective actions for fire-fighters	:	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
Special protective equipment for fire-fighters	:	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	:	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment.
For emergency responders	:	If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
Environmental precautions	:	Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill	:	Move containers from spill area. Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor.
Large spill	:	Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures	:	Put on appropriate personal protective equipment (see Section 8).
Advice on general occupational hygiene	:	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

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

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Petrolatum	None

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

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

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

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

Skin protection

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

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

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks

involved and should be approved by a specialist before handling this product.

Respiratory protection : Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties

Appearance

Physical state	:	Semi-solid
Colour	:	Light yellow
Odour	:	Not available.
Odour threshold	:	Not available.
pH	:	Not available
Melting point	:	Not applicable
Boiling point	:	Not available.
Flash point	:	>200°F/93.3°C
Evaporation rate	:	Not available.
Flammability (solid, gas)	:	Not available.
Lower and upper explosive (flammable) limits	:	**Lower:** Not available. **Upper:** Not available.
Vapour pressure	:	Not applicable.
Vapour density	:	Not available.
Relative density	:	0.8475
Solubility	:	Not available.
Solubility in water	:	Not available.
Partition coefficient: n-octanol/water	:	Not available.
Auto-ignition temperature	:	Not available.
Decomposition temperature	:	Not available.
Viscosity	:	**Dynamic:** Not available. **Kinematic:** Not available.

Section 10. Stability and reactivity

Reactivity	:	No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	:	The product is stable.
Possibility of hazardous reactions	:	Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	:	No specific data.
Incompatible materials	:	No specific data.
Hazardous decomposition products	:	Under normal conditions of storage and use, hazardous decomposition products should not be produced. Under normal

conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Conclusion/Summary : Very low toxicity to humans or animals.

Irritation/Corrosion

Conclusion/Summary
Skin : The mixture is not an irritant for the skin.
Eyes : The mixture is not an irritant for eyes.
Respiratory : No inhalation irritancy studies have been performed on the mixture. Based on the composition as indicated in section 3, it is not likely that this mixture will cause irritation of the respiratory tract.

Sensitisation

Conclusion/Summary
Skin : No sensitization studies have been performed on the mixture. Based on the composition as indicated in section 3, it's not likely that the mixture will cause sensitisation by skin contact

Respiratory : No inhalation irritancy studies have been performed on the mixture. Based on the composition as indicated in section 3, it is not likely that this mixture will cause irritation of the respiratory tract.

Mutagenicity

Conclusion/Summary : Not applicable.

Carcinogenicity

Conclusion/Summary : Not classified or listed by IARC, NTP, OSHA, EU and ACGIH.

Reproductive toxicity

Conclusion/Summary : Not applicable.

Teratogenicity

Conclusion/Summary : Not applicable.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)
Not available.

Aspiration hazard
Not available.

Information on the likely routes of exposure	:	Not available.

Potential acute health effects

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

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	:	No specific data.
Inhalation	:	No specific data.
Skin contact	:	No specific data.
Ingestion	:	No specific data.

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

Short term exposure

Potential immediate effects	:	Not available.
Potential delayed effects	:	Not available.

Long term exposure

Potential immediate effects	:	Not available.
Potential delayed effects	:	Not available.

Potential chronic health effects

Conclusion/Summary	:	Very low toxicity to humans or animals.
General	:	No known significant effects or critical hazards.
Carcinogenicity	:	No known significant effects or critical hazards.
Mutagenicity	:	No known significant effects or critical hazards.
Teratogenicity	:	No known significant effects or critical hazards.
Developmental effects	:	No known significant effects or critical hazards.
Fertility effects	:	No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Not available.

Section 12. Ecological information

Toxicity

Conclusion/Summary : No known significant effects or critical hazards.

Persistence and degradability

Conclusion/Summary : No known significant effects or critical hazards.

Mobility in soil

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

RCRA classification : No known significant effects or critical hazards.

United States - RCRA Acute hazardous waste "P" List: Not listed

United States - RCRA Toxic hazardous waste "U" List: Not listed

Section 14. Transport information

FOR SHIPMENT IN CONSUMER PACKAGING	Ground	Water	Air
UN number	N/A	N/A	N/A

UN proper shipping name	Not regulated.	Not regulated.	Not regulated.
Transport hazard class(es)	Not regulated.	Not regulated.	Not regulated.
Packing group	N/A	N/A	N/A
Environmental hazards	None	None	None
Additional information	Not regulated.	Not regulated. **Marine pollutant:** No.	Not regulated.

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 have been trained in the event of an accident or spillage.'

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

Not available.

Section 15. Regulatory information

U.S. Federal regulations :

United States - TSCA 12(b) - Chemical export notification: None of the components are listed.
United States - TSCA 4(a) - Final Test Rules: Not listed
United States - TSCA 4(a) - ITC Priority list: Not listed
United States - TSCA 4(a) - Proposed test rules: Not listed
United States - TSCA 4(f) - Priority risk review: Not listed
United States - TSCA 5(a)2 - Final significant new use rules: Not listed
United States - TSCA 5(a)2 - Proposed significant new use rules: Not listed
United States - TSCA 5(e) - Substances consent order: Not listed
United States - TSCA 6 - Final risk management: Not listed
United States - TSCA 6 - Proposed risk management: Not listed
United States - TSCA 8(a) - Chemical risk rules: Not listed
United States - TSCA 8(a) - Dioxin/Furan precursor: Not listed
United States - TSCA 8(a) - Chemical Data Reporting (CDR): Not determined
United States - TSCA 8(a) - Preliminary assessment report (PAIR): Not listed
United States - TSCA 8(c) - Significant adverse reaction (SAR): Not listed
United States - TSCA 8(d) - Health and safety studies: Not listed
United States - EPA Clean water act (CWA) section 307 - Priority pollutants: Not listed
United States - EPA Clean water act (CWA) section 311 - Hazardous substances: Not listed
United States - EPA Clean air act (CAA) section 112 - Accidental release prevention - Flammable substances: Not

listed
United States - EPA Clean air act (CAA) section 112 - Accidental release prevention - Toxic substances: Not listed
United States - Department of commerce - Precursor chemical: Not listed

Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)	:	Not listed
Clean Air Act Section 602 Class I Substances	:	Not listed
Clean Air Act Section 602 Class II Substances	:	Not listed
DEA List I Chemicals (Precursor Chemicals)	:	Not listed
DEA List II Chemicals (Essential Chemicals)	:	Not listed

SARA 302/304

: Not applicable.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

Not available

SARA 313

None of the components are listed.

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.

US California 22CCR Appendix X Substances

Not listed

California Prop. 65 : Not applicable

United States inventory (TSCA 8b)	:	Exempted
Canada inventory	:	Not determined.

International regulations

International lists	:	**Australia inventory (AICS):** Not determined. **Taiwan inventory (CSNN):** Not determined. **Malaysia Inventory (EHS Register):** Not determined. **Japan inventory:** Not determined. **China inventory (IECSC):** Not determined. **Korea inventory:** Not determined. **New Zealand Inventory of Chemicals (NZIoC):** Not determined. **Philippines inventory (PICCS):** 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

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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

History

Date of printing	:	08/02/2015
Date of issue/Date of revision	:	08/02/2015
Date of previous issue	:	00/00/0000
Version	:	1.0
Prepared by	:	Global Product Compliance Unilever Regulatory Affairs 40 Merritt Blvd Trumbull, CT 06611 USA
Key to abbreviations	:	ATE = Acute Toxicity Estimate ACGIH = American Conference of Governmental & Industrial Hygienists AH = Acute Hazard BCF = Bioconcentration Factor CAA = Clean Air Act CARB = California Air Resources Board CCR = California Code of Regulations CERCLA = Comprehensive Environmental Response, Compensation & Liability Act CFR = Code of Federal Regulations CH = Chronic Hazard

CWA = Clean Water Act
DEA = Drug Enforcement Administration
DOT = Department of Transportation
EC = European Commission
EPCRA = Emergency Planning and Community Right‑To‑Know Act
EST = Eastern Standard Time
F = Fire
HAPS = Hazardous Air Pollutants
HCS = Hazard Communication Standard
HMIS = Hazardous Materials Information System
HVOC = High Volatile Organic Compound
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IARC = International Agency for the Research of Cancer
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
ICAO = International Civil Aviation Organization
IMDG = International Maritime Dangerous Goods
IMO = International Maritime Organization
ITC = Interagency Testing Committee (TSCA)
KOC = Organic Carbon/Water Partition Constant
LogPow = logarithm of the octanol/water partition coefficient
LVOC = Low Volatile Organic Compound
MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
MPPCF = Million Particles Per Cubic Foot
N/A = Not Applicable
NFPA = National Fire Protection Association
NOEC = No Observable Effect Concentration
NTP = National Toxicology Program
OSHA = Occupation Safety & Health Administration
PEL = Permissible Exposure Limit
RCRA = Resource Conservation & Recovery Act
RQ = Reportable Quantity
RTK = Right-To-Know
SARA = Superfund Amendments & Reauthorization Act
STEL = Short-Term Exposure Limit
TBD = To Be Determined
TCC = Tagliabue Closed Cup
TCLP = Toxicity Characteristic Leaching Procedure
TDG = Transport of Dangerous Goods
TLV = Threshold Limit Value
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average
UN = United Nations

References **:** Evaluation method used for mixture classification: Calculation method.
Hazard Communication Standard 29 CFR 1910.1200 and Appendices

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.