

**Midlothian Medical Center**  
**5/23/2021**

**TABLE OF CONTENTS**

<b>SDS0217</b>	<b>Aloe Guard</b> HealthLink 5/6/2014	<b>1</b>
<b>SDS0421</b>	<b>Aspirin</b> Bayer Healthcare, LLC 11/13/2015	<b>2</b>
<b>SDS0443</b>	<b>BD SurePath™ Preservative Fluid</b> BD Diagnostics - TriPath 3/14/2014	<b>3</b>
<b>SDS0321</b>	<b>BD Vacutainer® Brand Tube with Dipotassium EDTA</b> Becton Dickinson 10/15/2018	<b>4</b>
<b>SDS0320</b>	<b>BD Vacutainer® SST Tubes</b> Becton Dickinson 3/9/2016	<b>5</b>
<b>SDS0430</b>	<b>Ceftriaxone for Injection</b> Hospira, A Pfizer Company 10/28/2016	<b>6</b>
<b>SDS0444</b>	<b>Chamber Brite</b> VWR International, LLC 10/30/2013	<b>7</b>
<b>SDS0410</b>	<b>CIDEX® OPA Solution</b> Advanced Sterilization Products 5/3/2013	<b>8</b>
<b>SDS0442</b>	<b>Clinitek Atlas Control Strips for Urine Chemistry</b> Siemens Healthcare Diagnostics, Inc 5/12/2017	<b>9</b>
<b>SDS2830</b>	<b>Clorox Broad Spectrum Quaternary Disinfectant Cleaner</b> The Clorox Company 1/5/2015	<b>10</b>
<b>SDS0367</b>	<b>CONSULT® Strep A Test</b> McKesson Medical-Surgical Inc. 1/13/2015	<b>11</b>

<b>SDS0408</b>	<b>Cyanocobalamin Injection, USP</b> Luitpold Pharmaceuticals, Inc 11/12/2015	<b>12</b>
<b>SDS0425</b>	<b>DAPTACEL</b> Sanofi Pasteur 1/22/2019	<b>13</b>
<b>SDS0422</b>	<b>DEPO-MEDROL</b> Pfizer Pharmaceuticals Group 3/23/2017	<b>14</b>
<b>SDS0531</b>	<b>Donnatal® Elixir</b> IriSys, Inc. 5/19/2015	<b>15</b>
<b>SDS0417</b>	<b>ENGRIX-B ADULT</b> GlaxoSmithKline US 5/29/2018	<b>16</b>
<b>SDS0431</b>	<b>Ethyl Chloride</b> Gebauer Company 4/23/2013	<b>17</b>
<b>SDS0447</b>	<b>Formalin solution, neutral buffered, 10%</b> Sigma-Aldrich 9/23/2016	<b>18</b>
<b>SDS0414</b>	<b>Gardasil®</b> Merck & Co., Inc 11/15/2016	<b>19</b>
<b>SDS0446</b>	<b>Hemocult Developer</b> Beckman Coulter, Inc. 4/15/2015	<b>20</b>
<b>SDS0416</b>	<b>HEPATYRIX</b> GlaxoSmithKline US 6/24/2014	<b>21</b>
<b>SDS0231</b>	<b>Influenza A &amp; B Test, Dipstick</b> Arlington Scientific Inc. 5/16/2014	<b>22</b>
<b>SDS0424</b>	<b>IPOL - Exemption Letter</b> Sanofi Pasteur 6/1/2013	<b>23</b>
<b>SDS0441</b>	<b>Isopropyl Rubbing Alcohol USP 70%</b> NDC, Inc. 2/24/2015	<b>24</b>
<b>SDS0429</b>	<b>Ketorolac Tromethamine Injection, USP</b> Hospira, A Pfizer Company 8/3/2016	<b>25</b>

<b>SDS0221</b>	<b>Lidocaine Hydrochloride and Epinephrine Injection, Solution</b> Hospira, A Pfizer Company 7/27/2017	<b>26</b>
<b>SDS0222</b>	<b>Lidocaine Hydrochloride Injection</b> Hospira, A Pfizer Company 7/26/2017	<b>27</b>
<b>SDS0436</b>	<b>Lidocaine Hydrochloride Oral Topical Solution, USP 2% (Viscous)</b> Akorn, Inc 7/7/2016	<b>28</b>
<b>SDS0415</b>	<b>M-M-R II Vaccine</b> Merck & Co., Inc 10/28/2016	<b>29</b>
<b>SDS0386</b>	<b>McKesson Hydrogen Peroxide, 3%</b> McKesson Medical-Surgical Inc. 10/29/2015	<b>30</b>
<b>SDS0412</b>	<b>McKesson Premium Instant Hand Sanitizer</b> McKesson Medical-Surgical Inc. 9/18/2015	<b>31</b>
<b>SDS0435</b>	<b>Milk of Magnesia</b> Bayer Healthcare, LLC 11/29/2007	<b>32</b>
<b>SDS0438</b>	<b>Nitrogen, Refrigerated Liquid</b> Praxair, Inc 10/21/2016	<b>33</b>
<b>SDS0439</b>	<b>Oxygen, compressed</b> Praxair, Inc 1/31/2013	<b>34</b>
<b>SDS0437</b>	<b>PNEUMOVAX™ 23</b> Merck & Co., Inc 4/1/2010	<b>35</b>
<b>SDS0451</b>	<b>Potassium Hydroxide</b> Cayman Chemical Company 10/1/2013	<b>36</b>
<b>SDS0423</b>	<b>Prevnar 13; PREVENAR; PREVENAR 13</b> Pfizer Pharmaceuticals Group 2/20/2018	<b>37</b>
<b>SDS0411</b>	<b>Pro Tech Disinfectant Cleaner/OASIS 146 MULTI-QUAT SANITIZER</b> Ecolab Inc. Institutional Division 8/16/2013	<b>38</b>
<b>SDS0440</b>	<b>Professional Lysol® Brand III Kills 99.9% of Viruses &amp; Bacteria** Disinfectant Spray, All Scents</b>	<b>39</b>

	NDC, Inc. 6/26/2015	
<b>SDS0420</b>	<b>Prolia</b> Amgen Inc 2/1/2013	<b>40</b>
<b>SDS0428</b>	<b>Promethazine HCl Injection, USP</b> West-Ward Pharmaceuticals 12/15/2018	<b>41</b>
<b>SDS0448</b>	<b>QUICKVUE IFOB TEST</b> Quidel Corporation 8/27/2007	<b>42</b>
<b>SDS0418</b>	<b>ROTARIX LYOPHILIZED VACCINE</b> GlaxoSmithKline US 5/16/2017	<b>43</b>
<b>SDS0413</b>	<b>SELECT Povidone Iodine, USP Swabsticks</b> McKesson Medical-Surgical Inc. 11/11/2015	<b>44</b>
<b>SDS0445</b>	<b>SODIUM CHLORIDE</b> VWR International, LLC 2/12/2015	<b>45</b>
<b>SDS0178</b>	<b>Super Sani-Cloth Germicidal Wipe</b> Nice-Pak/PDI, Inc. 12/7/2017	<b>46</b>
<b>SDS0427</b>	<b>Testosterone Cypionate Injection, USP C-III</b> West-Ward Pharmaceuticals 9/16/2016	<b>47</b>
<b>SDS0449</b>	<b>Tripedia®, Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed</b> Sanofi Pasteur 2/3/2011	<b>48</b>
<b>SDS0342</b>	<b>Virex TB Ready-To-Use Disinfectant Cleaner</b> Diversey, Inc 10/9/2014	<b>49</b>



Joining Forces to Serve the Healthcare Community



# Safety Data Sheet

**Issue Date:** 07-Jun-2013

**Revision Date:** 06-May-2014

**Version** 1

## 1. IDENTIFICATION

### Product Identifier

**Product Name** Aloe Guard

### Other means of identification

**Product Code** 7720, 7725, 7740, 7760

### Recommended use of the chemical and restrictions on use

**Recommended Use** Hand soap.

### Details of the supplier of the safety data sheet

### Emergency Telephone Number

**Emergency Telephone (24 hr)** Chemtrec: 1-800-424-9300

## 2. HAZARDS IDENTIFICATION

**EMERGENCY OVERVIEW:** The information below is for repeated and prolonged contact in an occupational setting. It is not likely to apply to normal product use.

**Appearance** Turquoise pearl viscous liquid

**Physical State** Liquid

**Odor** Floral

### Classification

Skin sensitization

Category 1

### Signal Word

Warning

### Hazard Statements

May cause an allergic skin reaction



### Precautionary Statements - Prevention

Contaminated work clothing should not be allowed out of the workplace

### Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

**Other Hazards**

Toxic to aquatic life with long lasting effects

**Unknown Acute Toxicity**

3.15% of the mixture consists of ingredient(s) of unknown toxicity

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%
Trade Secret	Proprietary	<10
Trade Secret	Proprietary	<1

\*\*If Chemical Name/CAS No is "proprietary" and/or Weight-% is listed as a range, the specific chemical identity and/or percentage of composition has been withheld as a trade secret.\*\*

### 4. FIRST-AID MEASURES

**First Aid Measures**

<b>Eye Contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If eye irritation persists: Get medical advice/attention.
<b>Skin Contact</b>	If skin irritation occurs, rinse affected area with water.
<b>Inhalation</b>	None under normal use conditions.
<b>Ingestion</b>	Give large quantities of water. Do not induce vomiting. Get medical attention.

**Most important symptoms and effects**

<b>Symptoms</b>	The product contains a small amount of sensitizing substance which may provoke an allergic reaction among sensitive individuals in contact with skin. Eye contact may be slightly irritating.
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**Indication of any immediate medical attention and special treatment needed**

<b>Notes to Physician</b>	Treat symptomatically.
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### 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**

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** Use personal protective equipment as required.

### Methods and material for containment and cleaning up

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

**Methods for Clean-Up** Flood area with water and then mop up. Dispose of in accordance with federal, state and local regulations.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

**Advice on Safe Handling** Handle in accordance with good industrial hygiene and safety practice. Do not destroy or deface the label. Contaminated work clothing should not be allowed out of the workplace.

### Conditions for safe storage, including any incompatibilities

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

**Incompatible Materials** None known based on information supplied.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Trade Secret	STEL: 20 mg/m <sup>3</sup> fume TWA: 10 mg/m <sup>3</sup> fume	(vacated) TWA: 10 mg/m <sup>3</sup> fume (vacated) STEL: 20 mg/m <sup>3</sup> fume	TWA: 10 mg/m <sup>3</sup> fume STEL: 20 mg/m <sup>3</sup> fume
Trade Secret	TWA: 10 mg/m <sup>3</sup> except stearates of toxic metals	-	-

### Appropriate engineering controls

**Engineering Controls** None under normal use conditions.

### Individual protection measures, such as personal protective equipment

**Eye/Face Protection** Avoid contact with eyes.

**Skin and Body Protection** No protective equipment is needed under normal use conditions.

**Respiratory Protection** No protective equipment is needed under normal use conditions.

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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

<b>Physical State</b>	Liquid	<b>Odor</b>	Floral
<b>Appearance</b>	Turquoise pearl viscous liquid	<b>Odor Threshold</b>	Not determined
<b>Color</b>	Turquoise		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	7.0-9.0	
Melting Point/Freezing Point	Not available	
Boiling Point/Boiling Range	Not determined	
Flash Point	None (will not burn)	
Evaporation Rate	Not determined	
Flammability (Solid, Gas)	n/a-liquid	
Upper Flammability Limits	Not determined	
Lower Flammability Limit	Not determined	
Vapor Pressure	Not available	
Vapor Density	Not determined	
Specific Gravity	1.014	(1=Water)
Water Solubility	Completely soluble	
Solubility in other solvents	Not determined	
Partition Coefficient	Not determined	
Auto-ignition Temperature	Not determined	
Decomposition Temperature	Not determined	
Kinematic Viscosity	Not determined	
Dynamic Viscosity	Not determined	
Explosive Properties	Not determined	
Oxidizing Properties	Not determined	

## 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.

### Conditions to Avoid

None known.

### Incompatible Materials

None known based on information supplied.

### Hazardous Decomposition Products

None known based on information supplied.



## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

<b>Product Information</b>	The information below is for repeated and prolonged contact in an occupational setting. It does not apply to normal product use
<b>Eye Contact</b>	Avoid contact with eyes.
<b>Skin Contact</b>	The product contains a small amount of sensitizing substance which may provoke an allergic reaction among sensitive individuals in contact with skin.
<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Ingestion</b>	Do not taste or swallow.

### Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Trade Secret	= 1288 mg/kg ( Rat )	= 580 mg/kg ( Rabbit )	> 3900 mg/m <sup>3</sup> ( Rat ) 1 h
Trade Secret	= 20000 mg/kg ( Rat )	= 20800 mg/kg ( Rabbit )	-
Trade Secret	> 5 g/kg ( Rat )	-	-
Trade Secret	= 1600 mg/kg ( Rat )	-	-
Trade Secret	= 3830 mg/kg ( Rat )	-	-
Trade Secret	= 1378 mg/kg ( Rat )	> 2 g/kg ( Rabbit )	-
Trade Secret	= 1410 mg/kg ( Rat )	-	-
Trade Secret	= 2600 mg/kg ( Rat )	> 2 g/kg ( Rabbit )	-
Trade Secret	= 2 g/kg ( Rat )	-	-
Trade Secret	= 2100 mg/kg ( Rat )	-	-

### Information on physical, chemical and toxicological effects

<b>Symptoms</b>	Please see section 4 of this SDS for symptoms.
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### Delayed and immediate effects as well as chronic effects from short and long-term exposure

<b>Sensitization</b>	May cause an allergic skin reaction.
<b>Carcinogenicity</b>	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.

### Numerical measures of toxicity

Not determined

<b>Unknown Acute Toxicity</b>	3.15% of the mixture consists of ingredient(s) of unknown toxicity.
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## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

Toxic to aquatic life with long lasting effects.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Trade Secret	53: 72 h <i>Desmodesmus subspicatus</i> mg/L EC50 30 - 100: 96 h <i>Desmodesmus subspicatus</i> mg/L EC50 117: 96 h <i>Pseudokirchneriella subcapitata</i> mg/L EC50 3.59 - 15.6: 96 h <i>Pseudokirchneriella subcapitata</i> mg/L EC50 static	8 - 12.5: 96 h <i>Pimephales promelas</i> mg/L LC50 static 15 - 18.9: 96 h <i>Pimephales promelas</i> mg/L LC50 static 22.1 - 22.8: 96 h <i>Pimephales promelas</i> mg/L LC50 static 4.3 - 8.5: 96 h <i>Oncorhynchus mykiss</i> mg/L LC50 static 4.62: 96 h <i>Oncorhynchus mykiss</i> mg/L LC50 flow-through 4.2: 96 h <i>Oncorhynchus mykiss</i> mg/L LC50 7.97: 96 h <i>Brachydanio rerio</i> mg/L LC50 flow-through 9.9 - 20.1: 96 h <i>Brachydanio rerio</i> mg/L LC50 semi-static 4.06 - 5.75: 96 h <i>Lepomis macrochirus</i> mg/L LC50 static 4.2 - 4.8: 96 h <i>Lepomis macrochirus</i> mg/L LC50 flow-through 4.5: 96 h <i>Lepomis macrochirus</i> mg/L LC50 5.8 - 7.5: 96 h <i>Pimephales promelas</i> mg/L LC50 static 10.2 - 22.5: 96 h <i>Pimephales promelas</i> mg/L LC50 semi-static 6.2 - 9.6: 96 h <i>Pimephales promelas</i> mg/L LC50 13.5 - 18.3: 96 h <i>Poecilia reticulata</i> mg/L LC50 semi-static 10.8 - 16.6: 96 h <i>Poecilia reticulata</i> mg/L LC50 static 1.31: 96 h <i>Cyprinus carpio</i> mg/L LC50 semi-static		1.8: 48 h <i>Daphnia magna</i> mg/L EC50
Trade Secret	19000: 96 h <i>Pseudokirchneriella subcapitata</i> mg/L EC50	51600: 96 h <i>Oncorhynchus mykiss</i> mg/L LC50 static 41 - 47: 96 h <i>Oncorhynchus mykiss</i> mL/L LC50 static 51400: 96 h <i>Pimephales promelas</i> mg/L LC50 static 710: 96 h <i>Pimephales promelas</i> mg/L LC50		10000: 24 h <i>Daphnia magna</i> mg/L EC50 1000: 48 h <i>Daphnia magna</i> mg/L EC50 Static
Trade Secret		0.13 - 1.0: 96 h <i>Oncorhynchus mykiss</i> mg/L LC50 static 1.3 - 2.1: 96 h <i>Lepomis macrochirus</i> mg/L LC50 static	EC50 = 1.6 mg/L 5 min	6.7 - 9: 48 h <i>Daphnia magna</i> mg/L EC50 Static
Trade Secret		725: 24 h <i>Lepomis macrochirus</i> mg/L LC50 209: 96 h <i>Cyprinus carpio</i> mg/L LC50 static		202: 24 h <i>Daphnia magna</i> mg/L LC50

### Persistence/Degradability

Not determined.

### Bioaccumulation

Not determined.

**Mobility**

Chemical Name	Partition Coefficient
Trade Secret	1.6

**Other Adverse Effects**

Not determined

**13. DISPOSAL CONSIDERATIONS****Waste Treatment Methods**

<b>Disposal of Wastes</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations.
<b>Contaminated Packaging</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations.

**14. TRANSPORT INFORMATION**

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

**DOT** Not regulated

**IATA** Not regulated

**IMDG**  
**Marine Pollutant** This material may meet the definition of a marine pollutant

**15. REGULATORY INFORMATION****International Inventories**

**TSCA** Listed

**Legend:**

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

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

*EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances*

*ENCS - Japan Existing and New Chemical Substances*

*IECSC - China Inventory of Existing Chemical Substances*

*KECL - Korean Existing and Evaluated Chemical Substances*

*PICCS - Philippines Inventory of Chemicals and Chemical Substances*

**US Federal Regulations****SARA 313**

Chemical Name	CAS No	Weight-%	SARA 313 - Threshold Values %
Trade Secret -		0.1 - 1	1.0

**US State Regulations****U.S. State Right-to-Know Regulations**

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Trade Secret	X		X
Trade Secret	X	X	X

**16. OTHER INFORMATION****NFPA****Health Hazards****Flammability****Instability****Special Hazards****HMIS**

Not determined

Not determined

Not determined

Not determined

**Health Hazards****Flammability****Physical Hazards****Personal Protection**

1

0

0

A = Goggles

**Issue Date:**

07-Jun-2013

**Revision Date:**

06-May-2014

**Revision Note:**

New format

**Disclaimer**

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

**End of Safety Data Sheet**



# SAFETY DATA SHEET

## Bayer Genuine Aspirin Tablet 325mg

122000006025

Version 1.0

Revision Date 11/13/2015

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

#### Product information

**Product Name:** Bayer Genuine Aspirin Tablet 325mg  
**Synonyms:** BAYER ASPIRIN CAPLETS 325MG  
**SDS Number:** 122000006025

**Use** : Medicinal products

#### Company

BAYER HEALTHCARE LLC  
 Consumer Care  
 100 Bayer Boulevard PO Box 915  
 Whippany, NJ 07981-0915  
 UNITED STATES OF AMERICA  
 (800) 743-5423

**In case of emergency:** (800) 331-4536  
 Chemtrec: (800) 424-9300  
 BAYER INFORMATION PHONE: (800) 331-4536 OR (800) 743-5423

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

**Colour:** white **Form:** tablet

#### GHS Classification:

**Acute toxicity (Ingestion)** : Category 4

#### GHS Label element:

**Hazard pictograms** :



**Signal word** : Warning

**Hazard statements** : H302 Harmful if swallowed.

**Precautionary statements** : **Prevention:**  
 P264 Wash skin thoroughly after handling.  
 P270 Do not eat, drink or smoke when using this product.

SAFETY DATA SHEET  
**Bayer Genuine Aspirin Tablet 325mg**

122000006025

Version 1.0

Revision Date 11/13/2015

**Response:**

P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/  
physician if you feel unwell.  
P330 Rinse mouth.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal  
plant.

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**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Weight percent	Components	CAS-No.
83.3%	Acetylsalicylic acid	50-78-2

**Other Ingredients**

Weight percent	Components	CAS-No.
8.25%	Starch	9005-25-8
8.25%	Cellulose	9004-34-6

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**4. FIRST AID MEASURES**

**General advice:** No hazards which require special first aid measures.

**If inhaled:** Not an expected entry route.

**In case of skin contact:** No hazards which require special first aid measures.

**In case of eye contact:** No hazards which require special first aid measures.

**If swallowed:** In case of overdose, contact your regional poison control center or physician immediately. Contact U.S. Poison Control Center at 1-800-222-1222.

**Contact Number:** Use the Bayer Emergency Number in Section 1

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**5. FIREFIGHTING MEASURES**

**Suitable extinguishing media:** Any

**Specific hazards during firefighting:** Fire may cause the release of: Carbon monoxide (CO)  
Carbon dioxide (CO<sub>2</sub>)

**Special protective equipment for firefighters:** In the event of fire, wear self-contained breathing

SAFETY DATA SHEET  
**Bayer Genuine Aspirin Tablet 325mg**

122000006025

Version 1.0

Revision Date 11/13/2015

apparatus.

**Further information:** Prevent fire extinguishing water from contaminating surface water or the ground water system.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Use personal protective equipment.

**Methods for cleaning up:** Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

**Additional advice:** Avoid dust formation.

**Further Accidental Release Notes**      Avoid dust formation.

## 7. HANDLING AND STORAGE

**Handling:**

Industrial uses: Avoid dust formation. Avoid contact with skin, eyes and clothing.

No special protective measures against fire required.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Acetylsalicylic acid (50-78-2)**

US. ACGIH Threshold Limit Values

Time Weighted Average (TWA): 5 mg/m<sup>3</sup>

US. NIOSH: Pocket Guide to Chemical Hazards

Recommended exposure limit (REL): 5 mg/m<sup>3</sup>

**Starch (9005-25-8)**

US. ACGIH Threshold Limit Values

Time Weighted Average (TWA): 10 mg/m<sup>3</sup>

US. NIOSH: Pocket Guide to Chemical Hazards

Recommended exposure limit (REL): 10 mg/m<sup>3</sup> (Total)

US. NIOSH: Pocket Guide to Chemical Hazards

Recommended exposure limit (REL): 5 mg/m<sup>3</sup> (Respirable.)

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

Permissible exposure limit: 15 mg/m<sup>3</sup> (Total dust.)

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

Permissible exposure limit: 5 mg/m<sup>3</sup> (Respirable fraction.)

**Cellulose (9004-34-6)**

US. ACGIH Threshold Limit Values

Time Weighted Average (TWA): 10 mg/m<sup>3</sup>

# SAFETY DATA SHEET

## Bayer Genuine Aspirin Tablet 325mg

122000006025

Version 1.0

Revision Date 11/13/2015

US. NIOSH: Pocket Guide to Chemical Hazards  
 Recommended exposure limit (REL): 10 mg/m3 (Total)  
 US. NIOSH: Pocket Guide to Chemical Hazards  
 Recommended exposure limit (REL): 5 mg/m3 (Respirable.)  
 US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)  
 Permissible exposure limit: 5 mg/m3 (Respirable fraction.)  
 US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)  
 Permissible exposure limit: 15 mg/m3 (Total dust.)

### Respiratory protection:

Recommended Filter type: HEPA

None required for consumer use of this product.

### Hand protection:

Chemically resistant gloves.

None required for consumer use of this product.

### Eye protection:

Safety glasses

None required for consumer use of this product.

### Other protective measures:

No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients.

For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet.

Wear suitable protective equipment.

Please consult label for end-user requirements.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	tablet
Colour:	white
Odour:	No applicable information is available
Odour Threshold:	No applicable information is available
Melting point:	No applicable information is available
Boiling point/boiling range:	No applicable information is available
Density:	No applicable information is available
Bulk density:	No applicable information is available
Vapour pressure:	No applicable information is available
Viscosity, dynamic:	No applicable information is available
Viscosity, kinematic:	No applicable information is available
Flow time:	No applicable information is available
Surface tension:	No applicable information is available
Miscibility with water:	No applicable information is available



SAFETY DATA SHEET  
**Bayer Genuine Aspirin Tablet 325mg**

122000006025

Version 1.0

Revision Date 11/13/2015

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Water solubility:	No applicable information is available
pH:	No applicable information is available
Relative density:	No applicable information is available
Partition coefficient:	No applicable information is available
Solubility(ies):	No applicable information is available
Flash point:	No applicable information is available
Flammability (solid, gas):	No applicable information is available
Ignition temperature:	No applicable information is available
Explosion limits:	No applicable information is available

---

## 10. STABILITY AND REACTIVITY

**Conditions to avoid:** No data available

**Materials to avoid:** Oxidizing agents

**Hazardous reactions:** None known.

**Thermal decomposition:**

No data available

**Hazardous decomposition products:**

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

**Oxidizing properties:**

No statements available.

**Impact sensitivity:**

No data available

---

## 11. TOXICOLOGICAL INFORMATION

**Acute oral toxicity:**

Acute toxicity estimate (ATE) 1,476 mg/kg

Method: Calculation method

**Acute inhalation toxicity:**

Cellulose

LC50 Rat: > 5.05 mg/l, 4 h

May be harmful if inhaled.

SAFETY DATA SHEET  
**Bayer Genuine Aspirin Tablet 325mg**

122000006025

Version 1.0

Revision Date 11/13/2015

**Acute dermal toxicity:**

Cellulose

LD50 Rabbit: &gt; 2,000 mg/kg

May be harmful in contact with skin.

**Acute toxicity (other routes of administration):**

Starch

LD50 intraperitoneal Mouse: 6,600 mg/kg

**Skin irritation:**

Acetylsalicylic acid

Rabbit

Result: Mild skin irritation

Starch

Rabbit

Result: Mild skin irritation

Method: Draize Test

Cellulose

Rabbit

Result: No skin irritation

**Eye irritation:**

Acetylsalicylic acid

Rabbit

Result: Mild eye irritation

Cellulose

Rabbit

Result: No eye irritation

**Sensitisation:**

Cellulose

Skin sensitization guinea pig

Result: Did not cause sensitisation on laboratory animals.

**Genotoxicity in vitro:**

Acetylsalicylic acid

Ames test

Result: negative

Cellulose

Ames test

Result: negative

**Genotoxicity in vivo:**

Cellulose

Mouse

Result: No indication of mutagenic effects.

**Pharmaceutic effects:**

Acetylsalicylic acid

Analgesic Anti-inflammatory (Antiphlogistic) antipyretic

**SAFETY DATA SHEET**  
**Bayer Genuine Aspirin Tablet 325mg**

122000006025

Version 1.0

Revision Date 11/13/2015

**Carcinogenicity:**

No Carcinogenic substances as defined by IARC, NTP and/or OSHA

**STOT - single exposure:**

No data available

**STOT - repeated exposure:**

No data available

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**12. ECOLOGICAL INFORMATION**
**General advice:**

Ecological injuries are not known or expected under normal use.

**Toxicity to fish:**

Acetylsalicylic acid

Acute Fish toxicity: LC0 &gt; 100 mg/l

Test species: Danio rerio (zebra fish)

Method: Directive 67/548/EEC, Annex V, C.1.

Cellulose

Acute Fish toxicity: LC50 &gt; 100 mg/l

Test species: Oncorhynchus mykiss (rainbow trout) Duration of test: 96 h

**Toxicity to daphnia and other aquatic invertebrates:**

Acetylsalicylic acid

EC50 &gt; 100 mg/l

Test species: Daphnia magna (Water flea) Duration of test: 48 h

Cellulose

LC50 &gt; 100 mg/l

Test species: Daphnia magna (Water flea) Duration of test: 48 h

**Toxicity to algae:**

Cellulose

EC50 &gt; 100 mg/l

Duration of test: 96 h

NOEC 12.5 mg/l

Duration of test: 96 h

**Toxicity to bacteria:**

Acetylsalicylic acid

EC50 &gt; 10,000 mg/l

tested on: activated sludge micro-organism

Method: OECD 209

**Biodegradability:**

Acetylsalicylic acid

98 %, 28 d rapidly biodegradable

Method: OECD 301 D

**SAFETY DATA SHEET**  
**Bayer Genuine Aspirin Tablet 325mg**

122000006025

Version 1.0

Revision Date 11/13/2015

Cellulose

inherently degradable

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### 13. DISPOSAL CONSIDERATIONS

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

---

### 14. TRANSPORT INFORMATION

**Land transport (CFR)**

non-regulated

**US Sea transport (IMDG)**

non-regulated

**US Air transport (ICAO / IATA cargo aircraft only)**

non-regulated

**US Air transport (ICAO / IATA passenger and cargo aircraft)**

non-regulated

**International IATA**

IMDG

non-regulated

non-regulated

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### 15. REGULATORY INFORMATION

**Other regulations:** No statements available.

**US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)**

**Components**

None

**US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required**

**Components**

None

**US. EPA CERCLA Hazardous Substances (40 CFR 302) Components**

None

**Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists**

**SAFETY DATA SHEET**  
**Bayer Genuine Aspirin Tablet 325mg**

122000006025

Version 1.0

Revision Date 11/13/2015

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Weight percent	Components	CAS-No.
5 - 10%	Starch	9005-25-8
5 - 10%	Cellulose	9004-34-6
60 - 100%	Acetylsalicylic acid	50-78-2

**California Prop. 65****WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive ha**

Weight percent	Components	CAS-No.
60 - 100%	Acetylsalicylic acid	50-78-2

**OSHA Hazcom Standard Rating**

Not subject to OSHA

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**16. OTHER INFORMATION****Further information**

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





## Safety Data Sheet acc. to OSHA HCS

Page 1/11

Date Prepared: 03/14/2014

Reviewed On: 03/14/2014

### 1 Identification

- **Product Identifier**
- **Product Name:** BD SurePath™ Preservative Fluid
- **Catalog Number:** 490522
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** *In-vitro Diagnostics*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
BD Diagnostics - TriPath  
780 Plantation Drive  
Burlington, NC 27215  
Telephone: (336) 290 - 8300 or 866 - TriPath (option#1)
- **Information Department:** Technical Service
- **Emergency telephone number:**  
(336) 290-8300 or (866) TriPath (option # 1), or ChemTrec at (800) 424-9300.

### 2 Hazard(s) identification

- **Classification of the substance or mixture**

GHS02 Flame

*Flam. Liq. 3 H226 Flammable liquid and vapour.*

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

*Xn; Harmful**R22: Harmful if swallowed.**R10: Flammable.*

- **Classification system:**

*The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.*

- **Label elements**

- **GHS label elements**

*The product is classified and labeled according to the Globally Harmonized System (GHS).*

- **Hazard pictograms**

GHS02

- **Signal word** *Warning*

- **Hazard statements**

*H226 Flammable liquid and vapour.*

- **Precautionary statements**

*P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.*

(Contd. on page 2)

US



## Safety Data Sheet acc. to OSHA HCS

Page 2/11

Date Prepared: 03/14/2014

Reviewed On: 03/14/2014

**Product Name: BD SurePath™ Preservative Fluid**

(Contd. of page 1)

- P241 Use explosion-proof electrical/ventilating/lighting/equipment.  
 P280 Wear protective gloves/protective clothing/eye protection/face protection.  
 P240 Ground/bond container and receiving equipment.  
 P233 Keep container tightly closed.  
 P242 Use only non-sparking tools.  
 P243 Take precautionary measures against static discharge.  
 P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.  
 P370+P378 In case of fire: Use for extinction: CO<sub>2</sub>, powder or water spray.  
 P403+P235 Store in a well-ventilated place. Keep cool.  
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

• **NFPA ratings (scale 0-4)**



Health = 0  
Flammability = 3  
Reactivity = 0

• **HMIS ratings (scale 0-4)**



HEALTH 0 Health = 0  
FIRE 3 Flammability = 3  
REACTIVITY 0 Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization: Mixture**
- **Description:** Mixture consisting of the following components.

• **Dangerous Components:**

CAS: 64-17-5 EINECS: 200-578-6	ethanol	F R10	21.7%
CAS: 67-56-1 EINECS: 200-659-6	methanol	T R23/24/25-39/23/24/25; F R11	1.2%
CAS: 67-63-0 EINECS: 200-661-7	isopropanol	Xi R36; F R11 R67	1.1%

- **Additional information** Risk phrases refer to section 15.

### 4 First-aid measures

- **Description of first aid measures**
- **General information** Immediately remove contaminated clothing.

(Contd. on page 3)

US





## Safety Data Sheet acc. to OSHA HCS

Page 3/11

Date Prepared: 03/14/2014

Reviewed On: 03/14/2014

**Product Name: BD SurePath™ Preservative Fluid**

(Contd. of page 2)

- **After inhalation**  
Supply fresh air and seek medical advice.  
In case of unconsciousness place patient on side position for transportation.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact**  
Rinse opened eye for 15 minutes under running water. Then consult a doctor.
- **After swallowing**  
Do not induce vomiting; immediately call for medical help.  
Drink copious amounts of water and provide fresh air. Immediately call a doctor.
- **Information for doctor** Show this product label or this MSDS.
- **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents**  
CO<sub>2</sub>, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **Special hazards arising from the substance or mixture**  
No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:**  
Wear fully protective suit.  
Wear self-contained respiratory protective device.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Use respiratory protective device.  
Wear protective clothing.
- **Environmental precautions:** Wipe up with damp sponge or mop.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

US

(Contd. on page 4)



## Safety Data Sheet acc. to OSHA HCS

Page 4/11

Date Prepared: 03/14/2014

Reviewed On: 03/14/2014

**Product Name: BD SurePath™ Preservative Fluid**

(Contd. of page 3)

### 7 Handling and storage

- **Handling**
- **Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **Information about protection against explosions and fires:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** 15 - 30 °C
- **Information about storage in one common storage facility:**  
Store away from oxidizing agents.
- **Further information about storage conditions:**  
Store in cool, dry conditions in well sealed containers.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical systems:**  
No further data; see Section 7.

- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

#### 64-17-5 ethanol

PEL	1900 mg/m <sup>3</sup> , 1000 ppm
REL	1900 mg/m <sup>3</sup> , 1000 ppm
TLV	1880 mg/m <sup>3</sup> , 1000 ppm

#### 67-56-1 methanol

PEL	260 mg/m <sup>3</sup> , 200 ppm
REL	Short-term value: 325 mg/m <sup>3</sup> , 250 ppm Long-term value: 260 mg/m <sup>3</sup> , 200 ppm Skin
TLV	Short-term value: 328 mg/m <sup>3</sup> , 250 ppm Long-term value: 262 mg/m <sup>3</sup> , 200 ppm Skin; BEI

#### 67-63-0 isopropanol

PEL	980 mg/m <sup>3</sup> , 400 ppm
REL	Short-term value: 1225 mg/m <sup>3</sup> , 500 ppm Long-term value: 980 mg/m <sup>3</sup> , 400 ppm

(Contd. on page 5)

US



## Safety Data Sheet acc. to OSHA HCS

Page 5/11

Date Prepared: 03/14/2014

Reviewed On: 03/14/2014

**Product Name: BD SurePath™ Preservative Fluid**

(Contd. of page 4)

TLV	Short-term value: 984 mg/m <sup>3</sup> , 400 ppm Long-term value: 492 mg/m <sup>3</sup> , 200 ppm BEI
-----	--

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal Protective Equipment**
- **General protective and hygienic measures**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing.  
Wash hands before breaks and at the end of work.
- **Breathing equipment:**  
In case of brief exposure, use a chemical fume hood or a NIOSH/MSHA-approved respirator.
- **Protection of hands:**

Chemical resistant gloves (i.e. nitrile, or equivalent).

- **Eye protection:** Safety glasses
- **Body protection:** Protective work clothing (lab coat).

### 9 Physical and chemical properties

#### · Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

<b>Form:</b>	Liquid
<b>Color:</b>	Clear Colorless
<b>Odor:</b>	Alcohol-like

<b>pH-value:</b>	7.2
------------------	-----

##### · Change in condition

<b>Melting point/Melting range:</b>	Not determined
<b>Boiling point/Boiling range:</b>	86 °C (187 °F)

<b>Flash point:</b>	35 °C (95 °F)
---------------------	---------------

<b>Ignition temperature:</b>	425.0 °C (797 °F)
------------------------------	-------------------

<b>Auto igniting:</b>	Product is not self igniting.
-----------------------	-------------------------------

<b>Danger of explosion:</b>	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
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##### · Explosion limits:

<b>Lower:</b>	3.5 Vol %
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(Contd. on page 6)

US



## Safety Data Sheet acc. to OSHA HCS

Page 6/11

Date Prepared: 03/14/2014

Reviewed On: 03/14/2014

**Product Name: BD SurePath™ Preservative Fluid**

(Contd. of page 5)

<b>Upper:</b>	15.0 Vol %
· <b>Vapor pressure at 20 °C (68 °F):</b>	59.0 hPa (44 mm Hg)
· <b>Density:</b>	Not determined
· <b>Solubility in / Miscibility with Water:</b>	Soluble
· <b>Solvent content:</b>	
<b>Organic solvents:</b>	24.2 %
<b>Water:</b>	74.7 %
· <b>Solids content:</b>	0.9 %
· <b>Other information</b>	No further relevant information available.

### 10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** Incompatible material: strong oxidizers.
- **Hazardous decomposition products:** No dangerous decomposition products known.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

 · **LD/LC50 values that are relevant for classification:**
**64-17-5 ethanol**

Oral	LD50	3450 mg/kg (MOU)
		7060 mg/kg (rat)

- **Primary irritant effect:**
- **on the skin:** No irritating effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Subacute to chronic toxicity:**  
Target organs: thyroid, kidney, ureter or bladder tumors.  
Target organ: liver
- **Additional toxicological information:**  
The product shows the following dangers according to internally approved calculation methods for preparations:

(Contd. on page 7)

US



## Safety Data Sheet acc. to OSHA HCS

Page 7/11

Date Prepared: 03/14/2014

Reviewed On: 03/14/2014

**Product Name: BD SurePath™ Preservative Fluid**

(Contd. of page 6)

**· Carcinogenic categories**
**· IARC (International Agency for Research on Cancer)**

67-63-0	isopropanol	3
50-00-0	formaldehyde	1

**· NTP (National Toxicology Program)**

None of the ingredients is listed.

### 12 Ecological information

**· Toxicity**
**· Aquatic toxicity:** This material is not expected to be toxic to aquatic life.

**· Persistence and degradability** No further relevant information available.

**· Behavior in environmental systems:**
**· Bioaccumulative potential** No further relevant information available.

**· Mobility in soil** No further relevant information available.

**· Ecotoxicological effects:**
**· Other information:**

The ecological effects have not been thoroughly investigated, but currently none have been identified.

**· Additional ecological information:**
**· General notes:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

**· Results of PBT and vPvB assessment**
**· PBT:** Not applicable.

**· vPvB:** Not applicable.

**· Other adverse effects** No further relevant information available.

### 13 Disposal considerations

**· Waste treatment methods**
**· Recommendation**

Must not be disposed of with solid waste.

Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements. RCRA hazardous waste - RCRA # D001 (ignitable).

**· Uncleaned packagings:**
**· Recommendation:** Disposal must be made according to state and federal regulations.

**· Recommended cleansing agent:** Water, if necessary with cleansing agents.

US

(Contd. on page 8)



## Safety Data Sheet acc. to OSHA HCS

Page 8/11

Date Prepared: 03/14/2014

Reviewed On: 03/14/2014

**Product Name: BD SurePath™ Preservative Fluid**

(Contd. of page 7)

### 14 Transport information

· <b>UN-Number</b>	
· <b>DOT, ADR, ADN, IMDG, IATA</b>	Void
· <b>UN proper shipping name</b>	
· <b>DOT, ADR, ADN, IMDG, IATA</b>	Void
· <b>Transport hazard class(es)</b>	
· <b>DOT, ADR, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>Packing group</b>	
· <b>DOT, ADR, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	49 CFR §173.150 Exceptions For Class 3 (Flammable) and Combustible Liquids being used .
· <b>DOT</b>	
· <b>Remarks:</b>	49CFR 173.150(e)(2) - States that aqueous solution of alcohol containing 24 percent or less alcohol by volume and no other hazardous material can be re-class as a combustible liquid and is not subject to the requirements.
· <b>IMDG</b>	
· <b>Remarks:</b>	IMDG Special Provision 144 - An aqueous solution containing not more than 24% alcohol by volume is not subject to the provisions of this code.
· <b>IATA</b>	
· <b>Remarks:</b>	IATA Special Provision A58 - Aqueous solutions containing 24% or less alcohol by volume is not subject to these regulations.
· <b>UN "Model Regulation":</b>	-

US

(Contd. on page 9)



## Safety Data Sheet acc. to OSHA HCS

Page 9/11

Date Prepared: 03/14/2014

Reviewed On: 03/14/2014

**Product Name: BD SurePath™ Preservative Fluid**

(Contd. of page 8)

### 15 Regulatory information

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

- **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

- **SARA Section 313 (specific toxic chemical listings)**

64-17-5 ethanol

67-56-1 methanol

67-63-0 isopropanol

- **TSCA (Toxic Substances Control Act)**

7732-18-5 water

64-17-5 ethanol

67-56-1 methanol

67-63-0 isopropanol

7647-14-5 sodium chloride

7758-11-4 potassium phosphate, dibasic

50-00-0 formaldehyde

- **California Proposition 65 - Chemicals known to cause cancer**

The concentration of formaldehyde is less than the OSHA regulated limit

50-00-0 formaldehyde

- **California Proposition 65 - Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **California Proposition 65 - Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **California Proposition 65 - Chemicals known to cause developmental toxicity:**

64-17-5 ethanol

- **Carcinogenic categories**

- **TLV (Threshold Limit Value established by ACGIH)**

64-17-5 ethanol

A4

67-63-0 isopropanol

A4

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

(Contd. on page 10)

US





## Safety Data Sheet acc. to OSHA HCS

Page 10/11

Date Prepared: 03/14/2014

Reviewed On: 03/14/2014

**Product Name: BD SurePath™ Preservative Fluid**

(Contd. of page 9)

- **Hazard pictograms**

GHS02

- **Signal word** Warning

- **Hazard statements**

H226 Flammable liquid and vapour.

- **Precautionary statements**

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

P241 Use explosion-proof electrical/ventilating/lighting/equipment.

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

P240 Ground/bond container and receiving equipment.

P233 Keep container tightly closed.

P242 Use only non-sparking tools.

P243 Take precautionary measures against static discharge.

P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.

P403+P235 Store in a well-ventilated place. Keep cool.

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

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 16 Other information

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities 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 can not guarantee that these are the only hazards that exist.

- **Department issuing MSDS:**

Environmental, Health &amp; Safety

Created by Michael J. Spinazzola

- **Contact:** Technical Service Representative

- **Date of preparation / last revision** 03/14/2014 / -

- **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organization

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

(Contd. on page 11)

US





**Safety Data Sheet**  
**acc. to OSHA HCS**

Page 11/11

Date Prepared: 03/14/2014

Reviewed On: 03/14/2014

**Product Name: BD SurePath™ Preservative Fluid**

(Contd. of page 10)

EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
Flam. Liq. 3: Flammable liquids, Hazard Category 3

US





Version: 18.1  
Last revised date: 10/15/2018

**Becton, Dickinson and Company**  
BD, Franklin Lakes, NJ  
07417 USA  
www.bd.com

# SAFETY DATA SHEET

## 1. Identification

### Product identifier

Product No.:	Product name:	Common name(s), synonym(s)
365974	TUBE MICRO W/MICROGARD EDTA LAV	BD Microtainer® K2EDTA Blood CollectionTube w/Microgard

### Other means of identification

SDS number: 088100181141

### Recommended use and restriction on use

**Recommended use:** Scientific and industrial laboratory use. For In Vitro Diagnostic Use.

**Restrictions on use:** For External Use Only

### Manufacturer/Importer/Supplier/Distributor Information

#### Manufacturer

Company Name: BD Diagnostics, Preanalytical Systems  
Address: 1 Becton Drive  
07417 Franklin Lakes, NJ USA  
Telephone: 1 800 631 0174  
Fax: 1 201 847 4866  
Contact Person: Technical Services  
E-mail: pas\_tech\_services@bd.com

**Emergency telephone number:** ChemTrec 1 800 424 9300

## 2. Hazard(s) identification

### Hazard Classification

#### Health Hazards

Acute toxicity (Inhalation - dust and mist) Category 4

### Label Elements

#### Hazard Symbol:



**Signal Word:** Warning



Version: 18.1  
Last revised date: 10/15/2018

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**Hazard Statement:** H332: Harmful if inhaled.

**Precautionary Statements**

**Prevention:** P261: Avoid breathing dust/fume/gas/mist/vapors/spray.  
P271: Use only outdoors or in a well-ventilated area.

**Response:** P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P312: Call a POISON CENTER/doctor if you feel unwell.

**Other hazards which do not result in GHS classification:** None.

### 3. Composition/information on ingredients

**Substances**

Chemical Identity	Common name and synonyms	CAS number	Content in percent (%)*
Dipotassium EDTA		25102-12-9	50 - <100%

\* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

### 4. First-aid measures

**General information:** No recommendation given, but first aid may still be required in case of accidental exposure, inhalation or ingestion of this chemical. If in doubt, GET MEDICAL ATTENTION PROMPTLY!

**Ingestion:** Seek medical advice. Due to the small packaging the risk of ingestion is minimal.

**Inhalation:** Dust irritates the respiratory system, and may cause coughing and difficulties in breathing. Move into fresh air and keep at rest. Get medical attention if symptoms persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

**Skin Contact:** Wash skin with soap and water. Due to the small packaging the risk of skin contact is minimal.

**Eye contact:** If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor. Due to the small packaging the risk of eye contact is minimal.

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

**Symptoms:** No specific symptoms noted.

**Hazards:** Low hazard for recommended handling by trained personnel.



Version: 18.1  
Last revised date: 10/15/2018

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#### Indication of immediate medical attention and special treatment needed

**Treatment:** Get medical attention if symptoms occur.

#### 5. Fire-fighting measures

**General Fire Hazards:** No unusual fire or explosion hazards noted.

#### Suitable (and unsuitable) extinguishing media

**Suitable extinguishing media:** Water spray, fog, CO<sub>2</sub>, dry chemical, or alcohol resistant foam.

**Unsuitable extinguishing media:** None known.

**Specific hazards arising from the chemical:** None known.

#### Special protective equipment and precautions for firefighters

**Special fire fighting procedures:** No unusual fire or explosion hazards noted.

**Special protective equipment for fire-fighters:** No specific precautions due to the small quantities handled. Use fire-extinguishing media appropriate for surrounding materials.

#### 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures:** Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid breathing dust/fume/gas/mist/vapors/spray.

**Methods and material for containment and cleaning up:** Sweep or scoop up and remove.

**Environmental Precautions:** Avoid release to the environment.

#### 7. Handling and storage

**Precautions for safe handling:** Wear appropriate personal protective equipment. Observe good laboratory hygiene practices. Low hazard for recommended handling by trained personnel.

**Conditions for safe storage, including any incompatibilities:** Store in a cool, dry place out of direct sunlight. Store in closed original container at temperatures between 4°C and 25°



Version: 18.1  
Last revised date: 10/15/2018

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## 8. Exposure controls/personal protection

### Control Parameters

#### Occupational Exposure Limits

None of the components have assigned exposure limits.

#### Appropriate Engineering Controls

Observe good industrial hygiene practices. Low hazard for recommended handling by trained personnel.

### Individual protection measures, such as personal protective equipment

#### General information:

No specific hygiene procedures noted, but good personal hygiene practices are always advisable, especially when working with chemicals.

#### Eye/face protection:

Avoid contact with eyes and prolonged skin contact. Protective gloves and goggles must be used if there is a risk of direct contact or splash.

#### Skin Protection

##### Hand Protection:

Use suitable protective gloves if risk of skin contact.

##### Other:

No data available.

#### Respiratory Protection:

Not relevant, due to the form of the product. The risk of inhalation of dust must be minimized as much as possible.

#### Hygiene measures:

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:

Crystalline Powder.

#### Form:

Crystalline Powder.

#### Color:

White

#### Odor:

Odorless

#### Odor threshold:

No data available.

#### pH:

No data available.

#### Melting point/freezing point:

The physical-chemical properties of this material have not been fully investigated.

#### Initial boiling point and boiling range:

The physical-chemical properties of this material have not been fully investigated.

#### Flash Point:

Not applicable

#### Evaporation rate:

No data available.

#### Flammability (solid, gas):

No data available.

#### Upper/lower limit on flammability or explosive limits



Version: 18.1  
Last revised date: 10/15/2018

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<b>Flammability limit - upper (%):</b>	No data available.
<b>Flammability limit - lower (%):</b>	No data available.
<b>Explosive limit - upper (%):</b>	No data available.
<b>Explosive limit - lower (%):</b>	No data available.
<b>Vapor pressure:</b>	The physical-chemical properties of this material have not been fully investigated.
<b>Vapor density:</b>	No data available.
<b>Relative density:</b>	The physical-chemical properties of this material have not been fully investigated.
<b>Solubility(ies)</b>	
<b>Solubility in water:</b>	The physical-chemical properties of this material have not been fully investigated.
<b>Solubility (other):</b>	Not applicable
<b>Partition coefficient (n-octanol/water):</b>	The physical-chemical properties of this material have not been fully investigated.
<b>Auto-ignition temperature:</b>	No data available.
<b>Decomposition temperature:</b>	No data available.
<b>Viscosity:</b>	Not determined.

## 10. Stability and reactivity

<b>Reactivity:</b>	Stable under normal temperature conditions and recommended use.
<b>Chemical Stability:</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions:</b>	None under normal conditions.
<b>Conditions to avoid:</b>	None known. None under normal conditions.
<b>Incompatible Materials:</b>	No common materials and contaminants with which the material may reasonably come into contact.
<b>Hazardous Decomposition Products:</b>	Material is stable under normal conditions.

## 11. Toxicological information

<b>General information:</b>	Under normal conditions of intended use, this material does not pose a risk to health.
<b>Information on likely routes of exposure</b>	
<b>Ingestion:</b>	Expected to be a low ingestion hazard.
<b>Inhalation:</b>	Harmful if inhaled. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.



Version: 18.1  
Last revised date: 10/15/2018

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BD, Franklin Lakes, NJ  
07417 USA  
www.bd.com

**Skin Contact:** Due to the small packaging the risk of skin contact is minimal.

**Eye contact:** Due to the small packaging the risk of eye contact is minimal.

**Symptoms related to the physical, chemical and toxicological characteristics**

**Ingestion:** No specific symptoms noted.

**Inhalation:** No specific symptoms noted.

**Skin Contact:** No specific symptoms noted.

**Eye contact:** No specific symptoms noted.

**Information on toxicological effects**

**Acute toxicity (list all possible routes of exposure)**

**Oral**

**Product:** No data available.

**Dermal**

**Product:** No data available.

**Inhalation**

**Product:** ATEmix: 1.5 mg/l

**Repeated dose toxicity**

**Product:** No data available.

**Skin Corrosion/Irritation**

**Product:** No data available.

**Serious Eye Damage/Eye Irritation**

**Product:** No data available.

**Respiratory or Skin Sensitization**

**Product:** No data available.

**Carcinogenicity**

**Product:** No data available.





Version: 18.1  
Last revised date: 10/15/2018

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**IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:**

No carcinogenic components identified

**US. National Toxicology Program (NTP) Report on Carcinogens:**

No carcinogenic components identified

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

No carcinogenic components identified

**Germ Cell Mutagenicity**

**In vitro**

**Product:** No data available.

**In vivo**

**Product:** No data available.

**Reproductive toxicity**

**Product:** No data available.

**Specific Target Organ Toxicity - Single Exposure**

**Product:** No data available.

**Specific Target Organ Toxicity - Repeated Exposure**

**Product:** No data available.

**Aspiration Hazard**

**Product:** No data available.

**Other effects:** No data available.

<b>12. Ecological information</b>
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**Ecotoxicity:**

**Acute hazards to the aquatic environment:**

**Fish**

**Product:** No data available.

**Aquatic Invertebrates**

**Product:** No data available.

**Chronic hazards to the aquatic environment:**

**Fish**



Version: 18.1  
Last revised date: 10/15/2018

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**Product:** No data available.

**Aquatic Invertebrates  
Product:**

No data available.

**Toxicity to Aquatic Plants  
Product:**

No data available.

#### **Persistence and Degradability**

**Biodegradation  
Product:**

No data available.

**BOD/COD Ratio  
Product:**

No data available.

#### **Bioaccumulative potential**

**Bioconcentration Factor (BCF)**

**Product:** No data available.

**Partition Coefficient n-octanol / water (log Kow)**

**Product:** Log Kow: The physical-chemical properties of this material have not been fully investigated.

**Mobility in soil:** No data available.

**Known or predicted distribution to environmental compartments**

Dipotassium EDTA No data available.

**Other adverse effects:** No data available.

### **13. Disposal considerations**

**Disposal instructions:** Dispose of waste and residues in accordance with local authority requirements.

**Contaminated Packaging:** No data available.



Version: 18.1  
Last revised date: 10/15/2018

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## 14. Transport information

DOTUN Number:	Not regulated.
UN Proper Shipping Name:	Not regulated.
Transport Hazard Class(es)	
Class:	Not regulated.
Label(s):	Not regulated.
Packing Group:	Not regulated.
Marine Pollutant:	Not regulated.
Limited quantity	Not regulated.
Excepted quantity	Not regulated.
Special precautions for user:	Not regulated.

### IMDG

UN Number:	Not regulated.
UN Proper Shipping Name:	Not regulated.
Transport Hazard Class(es)	
Class:	Not regulated.
Subsidiary risk:	Not regulated.
EmS No.:	Not regulated.
Packing Group:	Not regulated.
Environmental Hazards	
Marine Pollutant:	Not regulated.
Special precautions for user:	Not regulated.

### IATA

UN Number:	Not regulated.
Proper Shipping Name:	Not regulated.
Transport Hazard Class(es):	
Class:	Not regulated.
Subsidiary risk:	Not regulated.
Packing Group:	Not regulated.
Environmental Hazards	
Marine pollutant:	Not regulated.
Special precautions for user:	Not regulated.

## 15. Regulatory information

### US Federal Regulations

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**  
None present or none present in regulated quantities.

**US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**  
None present or none present in regulated quantities.



Version: 18.1  
Last revised date: 10/15/2018

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BD, Franklin Lakes, NJ  
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**CERCLA Hazardous Substance List (40 CFR 302.4):**

None present or none present in regulated quantities.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories**

Not listed.

**SARA 302 Extremely Hazardous Substance**

None present or none present in regulated quantities.

**SARA 304 Emergency Release Notification**

None present or none present in regulated quantities.

**SARA 311/312 Hazardous Chemical**

<u>Chemical Identity</u>	<u>Threshold Planning Quantity</u>
Dipotassium EDTA	10000 lbs

**SARA 313 (TRI Reporting)**

None present or none present in regulated quantities.

**Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)**

None present or none present in regulated quantities.

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

None present or none present in regulated quantities.

**US State Regulations**

**US. California Proposition 65**

No ingredient regulated by CA Prop 65 present.

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

No ingredient regulated by NJ Right-to-Know Law present.

**US. Massachusetts RTK - Substance List**

No ingredient regulated by MA Right-to-Know Law present.

**US. Pennsylvania RTK - Hazardous Substances**

No ingredient regulated by PA Right-to-Know Law present.

**US. Rhode Island RTK**

No ingredient regulated by RI Right-to-Know Law present.

<b>16. Other information, including date of preparation or last revision</b>
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**Issue Date:** 10/15/2018

**Version #:** 18.1



Version: 18.1  
Last revised date: 10/15/2018

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**Revision Information:**

**Further Information:** No data available.

**Disclaimer:**

Disclaimer:

The information contained herein has been obtained from various sources and is believed to be correct as of the date issued. However, neither BD nor any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability for a particular use 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. BD provides SDS in electronic form so the information may be more easily accessed. Due to the possibility of errors during transmission, BD makes no representations as to the completeness or accuracy of the information.





# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>BD Vacutainer® SST Tubes</b>
<b>Other means of identification</b>	
<b>Product code</b>	367782, 365967, 365968, 365978, 365979, 365906, 367966, 367968, 367974, 367976, 367977, 367979, 367981, 367983, 367985, 367986, 367987, 367988, 367989, 367991, 367997, 368013, 368015, 368016, 368159, 368825, 365979
<b>Recommended use</b>	Blood collection (In-Vitro Diagnostic) device
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company name</b>	BD Diagnostics, PreAnalytical Systems
<b>Address</b>	1 Becton Drive Franklin Lakes, NJ 07417-1885
<b>Telephone</b>	800-631-0174
<b>Contact person</b>	Technical Services
<b>Emergency telephone</b>	Chemtrec US 1-800-424-9300 EU 703-527-3887
<b>E-mail</b>	pas_tech_services@bd.com

## 2. Hazard(s) identification

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

## 3. Composition/information on ingredients

### Mixtures

Chemical name	CAS number	%
Hydrophobic amorphous fumed silica	68611-44-9	1-5
Quartz	14808-60-7	0.1-<1.0

<b>Composition comments</b>	All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. Components not listed are either non-hazardous or are below reportable limits.
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#### 4. First-aid measures

<b>Inhalation</b>	Due to the small packaging the risk of inhalation is minimal. In case of risk of inhalation of vapor/aerosols: Move person to fresh air.
<b>Skin contact</b>	Wash skin with soap and water. Get medical attention if irritation persists after washing.
<b>Eye contact</b>	Immediately flush with plenty of water for up to 15 minutes. Remove any contact lenses and open eyelids wide apart. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if any discomfort occurs.
<b>Most important symptoms/effects, acute and delayed</b>	May irritate eyes. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	By heating and fire, harmful vapors/gases may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace.
<b>Fire fighting equipment/instructions</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	Material may burn when exposed to sufficient heat.

#### 6. Accidental release measures

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

#### 7. Handling and storage

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

#### 8. Exposure controls/personal protection

##### Occupational exposure limits

##### US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
Quartz (CAS 14808-60-7)	TWA	0.3 mg/m <sup>3</sup>	Total dust.
		0.1 mg/m <sup>3</sup>	Respirable.
		2.4 mppcf	Respirable.

##### US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Quartz (CAS 14808-60-7)	TWA	0.025 mg/m <sup>3</sup>	Respirable fraction.



## US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Hydrophobic amorphous fumed silica (CAS 68611-44-9)	TWA	6 mg/m3	
Quartz (CAS 14808-60-7)	TWA	0.05 mg/m3	Respirable dust.
Biological limit values	No biological exposure limits noted for the ingredient(s).		
Exposure guidelines	No exposure limits noted for ingredient(s).		
Appropriate engineering controls	General ventilation normally adequate.		
Individual protection measures, such as personal protective equipment			
Eye/face protection	Risk of contact: Wear approved safety goggles.		
Skin protection			
Hand protection	For prolonged or repeated skin contact use suitable protective gloves. Nitrile gloves are recommended. Suitable gloves can be recommended by the glove supplier.		
Skin protection			
Other	No skin protection is ordinarily required under normal conditions of use. In accordance with good industrial hygiene practices, precautions should be taken to avoid skin contact.		
Respiratory protection	Under normal conditions, respirator is not normally required. If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.		
Thermal hazards	None.		
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.		

## 9. Physical and chemical properties

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

**Other information**

<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

**10. Stability and reactivity**

<b>Reactivity</b>	The product is stable and non reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Stable at normal conditions.
<b>Possibility of hazardous reactions</b>	Will not occur.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	None expected under normal conditions of use.

**11. Toxicological information****Information on likely routes of exposure**

<b>Inhalation</b>	Due to the small packaging the risk of inhalation is minimal. However: Vapors may irritate throat and respiratory system and cause coughing.
<b>Skin contact</b>	May cause skin irritation.
<b>Eye contact</b>	May cause eye irritation.
<b>Ingestion</b>	Ingestion may cause irritation and malaise.
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	May irritate eyes. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

**Information on toxicological effects**

<b>Acute toxicity</b>	Not expected to be acutely toxic.
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<b>Components</b>	<b>Species</b>	<b>Test Results</b>
Hydrophobic amorphous fumed silica (CAS 68611-44-9)		
<b>Acute</b>		
<i>Inhalation</i>		
LC50	Rat	0.45 mg/l, 4 hours

<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
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<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
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**Respiratory or skin sensitization**

<b>Respiratory sensitization</b>	Due to lack of data the classification is not possible.
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<b>Skin sensitization</b>	Due to lack of data the classification is not possible.
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<b>Germ cell mutagenicity</b>	Due to lack of data the classification is not possible.
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<b>Carcinogenicity</b>	Inhalation of quartz dust may cause cancer, however due to the physical form of the product, inhalation of dust is not likely.
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**IARC Monographs. Overall Evaluation of Carcinogenicity**

Hydrophobic amorphous fumed silica (CAS 68611-44-9)	3 Not classifiable as to carcinogenicity to humans.
Quartz (CAS 14808-60-7)	1 Carcinogenic to humans.

**NTP Report on Carcinogens**

Quartz (CAS 14808-60-7)	Known To Be Human Carcinogen.
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**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

<b>Reproductive toxicity</b>	Due to lack of data the classification is not possible.
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<b>Specific target organ toxicity - single exposure</b>	Due to lack of data the classification is not possible.
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<b>Specific target organ toxicity - repeated exposure</b>	Due to lack of data the classification is not possible.
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<b>Aspiration hazard</b>	Due to lack of data the classification is not possible.
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<b>Chronic effects</b>	None known.
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## 12. Ecological information

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

## 13. Disposal considerations

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

## 14. Transport information

<b>DOT</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.

## 15. Regulatory information

<b>US federal regulations</b>	This product is not hazardous according to OSHA 29CFR 1910.1200.
<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	Not regulated.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not regulated.
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	
Toluene (CAS 108-88-3)	LISTED
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA)</b>	
<b>Hazard categories</b>	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
<b>SARA 302 Extremely hazardous substance</b>	Not listed.
<b>SARA 311/312 Hazardous chemical</b>	No
<b>SARA 313 (TRI reporting)</b>	Not regulated.
<b>Other federal regulations</b>	
<b>Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List</b>	
Toluene (CAS 108-88-3)	
<b>Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)</b>	Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2) and Chemical Code Number**

Toluene (CAS 108-88-3) 6594

**Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))**

Toluene (CAS 108-88-3) 35 %WV

**DEA Exempt Chemical Mixtures Code Number**

Toluene (CAS 108-88-3) 594

**US state regulations** WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

**US. Massachusetts RTK - Substance List**

Hydrophobic amorphous fumed silica (CAS 68611-44-9)

Quartz (CAS 14808-60-7)

Toluene (CAS 108-88-3)

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

Quartz (CAS 14808-60-7)

Toluene (CAS 108-88-3)

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

Hydrophobic amorphous fumed silica (CAS 68611-44-9)

Quartz (CAS 14808-60-7)

Toluene (CAS 108-88-3)

**US. Rhode Island RTK**

Toluene (CAS 108-88-3)

**US. California Proposition 65**

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

Quartz (CAS 14808-60-7)

Toluene (CAS 108-88-3)

#### International Inventories

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

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

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

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

**Issue date** 01-October-2015

**Revision date** 09-March-2016

**Version #** 02

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

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

**NFPA ratings**



**List of abbreviations** LC50: Lethal Concentration, 50%.

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

**Disclaimer**

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

**This SDS contains revisions in the following section(s):**

1, 16.





## SAFETY DATA SHEET

Revision date: 28-Oct-2016

Version: 1.0

Page 1 of 7

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

#### Product Identifier

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

**Trade Name:** Not established  
**Chemical Family:** Cephalosporin antibiotic

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

**Intended Use:** Pharmaceutical product used as antibiotic agent

#### Details of the Supplier of the Safety Data Sheet

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

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

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

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

### 2. HAZARDS IDENTIFICATION

#### Classification of the Substance or Mixture

##### GHS - Classification

Respiratory Sensitization: Category 1  
 Skin Sensitization: Category 1

##### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

#### Label Elements

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

## SAFETY DATA SHEET

Material Name: Ceftriaxone for Injection (Hospira, Inc.)  
Revision date: 28-Oct-2016

Page 2 of 7  
Version: 1.0

**Precautionary Statements:**

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

**Other Hazards**

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

**Note:**

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

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Hazardous**

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

**Additional Information:**

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

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

### 4. FIRST AID MEASURES

**Description of First Aid Measures****Eye Contact:**

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

**Skin Contact:**

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



## SAFETY DATA SHEET

Material Name: Ceftriaxone for Injection (Hospira, Inc.)  
 Revision date: 28-Oct-2016

Page 3 of 7  
 Version: 1.0

**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

## SAFETY DATA SHEET

Material Name: Ceftriaxone for Injection (Hospira, Inc.)  
Revision date: 28-Oct-2016

Page 4 of 7  
Version: 1.0

## 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<sup>3</sup> to 3000ug/m<sup>3</sup>)

### Exposure Controls

#### Engineering Controls:

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

#### Personal Protective Equipment:

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

#### Hands:

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

#### Eyes:

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

#### Skin:

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

#### Respiratory protection:

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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical State:

Powder

#### Color:

White

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

C18-H18-N8-O7-S3.2Na

#### Molecular Weight:

661.60

#### Solvent Solubility:

No data available

#### Water Solubility:

No data available

#### pH:

No data available.

#### Melting/Freezing Point (°C):

No data available

#### Boiling Point (°C):

No data available.

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

#### Ceftriaxone sodium

No data available

#### Decomposition Temperature (°C):

No data available.

#### Evaporation Rate (Gram/s):

No data available

#### Vapor Pressure (kPa):

No data available

#### Vapor Density (g/ml):

No data available

#### Relative Density:

No data available

#### Viscosity:

No data available

#### Flammability:

#### Autoignition Temperature (Solid) (°C):

No data available

## SAFETY DATA SHEET

Material Name: Ceftriaxone for Injection (Hospira, Inc.)  
 Revision date: 28-Oct-2016

Page 5 of 7  
 Version: 1.0

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

## 10. STABILITY AND REACTIVITY

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

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

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

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

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

#### Ceftriaxone sodium

Rat Oral LD50 > 10 g/kg

Rat Subcutaneous LD50 > 5g/kg

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

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

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

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

#### Ceftriaxone sodium

2 Generation Reproductive Toxicity Rat Intravenous 586 mg/kg/day NOAEL No effects at maximum dose

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

#### Ceftriaxone sodium

## SAFETY DATA SHEET

Material Name: Ceftriaxone for Injection (Hospira, Inc.)  
Revision date: 28-Oct-2016

Page 6 of 7  
Version: 1.0

**11. TOXICOLOGICAL INFORMATION**

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

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

**12. ECOLOGICAL INFORMATION**

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

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

**13. DISPOSAL CONSIDERATIONS**

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

**14. TRANSPORT INFORMATION**

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

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

**15. REGULATORY INFORMATION**

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

## SAFETY DATA SHEET

Material Name: Ceftriaxone for Injection (Hospira, Inc.)  
Revision date: 28-Oct-2016

Page 7 of 7  
Version: 1.0

**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

### CHAMBER BRITE

OSHA Hazard Communication Standard  
29 CFR 1910.1200. Prepared to GHS Rev 3 and  
Hazardous Products Regulations (WHMIS 2015)  
Prepared to GHS Rev 5.

Date of issue: 11.20.2016  
Page: 1/13

#### SECTION 1: Identification

##### Product identifier used on the label:

**Product Name:** Chamber Brite

##### Other means of identification:

Trade name: Chamber Brite  
Product type: Powder

##### Recommended use of the chemical and restrictions on use:

**Recommended use:** Autoclave Cleaner Powder  
**Recommended restrictions:** Uses other than as recommended above.

##### Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party:

**Company Name:** LIMAT Chemicals Ltd,  
**Company Address:** Givat Chaim Meuchad, 38930  
Israel.  
**Company Telephone:** +972-4-6167730  
**Company Fax:** +972-4-6301304  
  
**Company Contact Name:** Chief Technologist - Raviv Brown  
**Company Contact Email:** limat@limat.co.il  
  
**Emergency phone number:** +972-50-7559731

#### SECTION 2: Hazard(s) identification

##### UNITED STATES:

Classification of the chemical in accordance with paragraph (d) of §1910.1200:

##### *Physical hazards*

No physical hazards known.

##### *Health hazards*

Serious eye damage/eye irritation, Category 2A.

##### *Environmental hazards*

Not adopted under OSHA paragraph (d) of §1910.1200



## Safety Data Sheet CHAMBER BRITE

OSHA Hazard Communication Standard  
29 CFR 1910.1200. Prepared to GHS Rev 3 and  
Hazardous Products Regulations (WHMIS 2015)  
Prepared to GHS Rev 5.

Date of issue: 11.20.2016  
Page: 2/13

**GHS Signal word:**

**WARNING**

**GHS Hazard statement(s):**

Causes serious eye irritation.

**GHS Hazard symbol(s):**



**GHS Precautionary statement(s):**

**Prevention:**

Wash skin thoroughly after handling.  
Wear eye protection/face protection.

**Response:**

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

**Storage:**

No storage precautionary statements required.

**Disposal:**

No disposal precautionary statements required.

**Hazard(s) not otherwise classified (HNOC):**

This product contains a component that may cause frostbite.

**Percentage of ingredient(s) of unknown acute toxicity:**

Not applicable

**HMIS (U.S.A.):**

Health	2
Fire	1
Reactivity	0
Personal Protection	E

**National Fire Protection Association NFPA (U.S.A.)**







## Safety Data Sheet CHAMBER BRITE

OSHA Hazard Communication Standard  
29 CFR 1910.1200. Prepared to GHS Rev 3 and  
Hazardous Products Regulations (WHMIS 2015)  
Prepared to GHS Rev 5.

Date of issue: 11.20.2016  
Page: 3/13

### CANADA:

#### WHMIS 1988 Classification

Class D2B: Toxic Material at  $\geq 1\%$  Moderate eye irritant

#### Classification of the chemical in accordance with Hazardous Products Regulations (WHMIS 2015):

##### *Physical hazards*

Not classified as a physical hazard under the Hazardous Products Regulations (WHMIS 2015).

##### *Health hazards*

Serious eye damage/eye irritation, Category 2A.

##### *Environmental hazards*

Not adopted under the Hazardous Products Regulations (WHMIS 2015).

#### GHS Signal word:

**WARNING.**

#### GHS Hazard statement(s):

Causes serious eye irritation.

#### GHS Hazard symbol(s):



#### GHS Precautionary statement(s):

Wash skin thoroughly after handling.  
Wear eye protection/face protection.  
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
If eye irritation persists: Get medical advice/attention.

#### Physical hazards not otherwise classified (PNOC):

None known.

#### Health hazard(s) not otherwise classified (HNOC):



## Safety Data Sheet CHAMBER BRITE

OSHA Hazard Communication Standard  
29 CFR 1910.1200. Prepared to GHS Rev 3 and  
Hazardous Products Regulations (WHMIS 2015)  
Prepared to GHS Rev 5.

Date of issue: 11.20.2016  
Page: 4/13

None known.

### SECTION 3: Composition/information on ingredients

**Mixture:** This battery is classified as an Article under OSHA Hazard Communication Standard 29CFR 1910.1200 and Hazardous Products Regulations (WHMIS 2015) and is not subject to the requirements for Information in the Supply Chain (Safety Data Sheets and Labels). While batteries may release hazardous substances if damaged, this is not an intended release as defined under these regulations.

Chemical name	CAS#	Concentration (weight %)
Citric Acid	77-92-9	90 – 100%

Note: The balance of the ingredients are not classified as hazardous or are below the concentration limit to be classified as hazardous, under the criteria of the Federal OSHA Hazard Communication Standard 29CFR 1910.1200 and Hazardous Products Regulations (WHMIS 2015)

### SECTION 4: First-aid measures

**Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion:**

- Eye contact:** Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be use. Get medical attention.
- Skin contact:** In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be use. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.
- Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
- Ingestion:** If large quantities of this material are swallowed, call a physician immediately. Do not induce vomiting. Never give anything by mouth to an unconscious person. If victim is conscious give water to drink.



## Safety Data Sheet CHAMBER BRITE

OSHA Hazard Communication Standard  
29 CFR 1910.1200. Prepared to GHS Rev 3 and  
Hazardous Products Regulations (WHMIS 2015)  
Prepared to GHS Rev 5.

Date of issue: 11.20.2016  
Page: 5/13

**Most important symptoms/effects, acute and delayed:** Causes irritation to skin, eyes and respiratory tract. May cause vomiting, diarrhoea, damage to tooth enamel, dermatitis.

**Indication of immediate medical attention and special treatment needed:** Notes to physician: No specific antidote, medical staff contacts Poisons Information Center. All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

### SECTION 5: Fire-fighting measures

**Suitable (and unsuitable) extinguishing media:**

**Suitable extinguishing media:** SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

**Unsuitable extinguishing media:** Do not use straight streams of water.

**Specific hazards arising from the chemical (e.g., nature of any hazardous combustion products):**

May be combustible at high temperature. Slightly flammable to flammable in presence of heat. Non-explosive in presence of shocks. Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

**Hazardous thermal decomposition products:** Carbon monoxide and carbon dioxide.

**Special protective equipment and precautions for fire-fighters:** Special protective equipment for fire fighters: Fire fighters should wear full protective clothing and self-contained breathing apparatus in positive pressure mode. Use water spray to cool unopened containers.

### SECTION 6: Accidental release measures

**Personal precautions, protective equipment and emergency procedures:** Evacuate personnel to safe areas. Wear protective clothing. Avoid contact with skin eyes and inhalation of vapors. Ventilate area of spill. Keep pure product away from drains, surface and ground water.

**Methods and materials for containment and cleaning up:**

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Stop leak if without risk. Do not get water inside container.



## Safety Data Sheet CHAMBER BRITE

OSHA Hazard Communication Standard  
29 CFR 1910.1200. Prepared to GHS Rev 3 and  
Hazardous Products Regulations (WHMIS 2015)  
Prepared to GHS Rev 5.

Date of issue: 11.20.2016  
Page: 6/13

### SECTION 7: Handling and storage

#### Precautions for safe handling:

**Handling:** Use with adequate ventilation. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

**Hygiene Measures:** 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 measures.

For precautions see section 2 and section 16.

**Conditions for safe storage, including any incompatibles:** Store in cool, dry well-ventilated area. Keep away from incompatible materials (see section 10). Keep product in a dry and well-ventilated place. Packets which are opened must be carefully resealed and kept upright to prevent leakage.

### SECTION 8: Exposure controls/personal protection

OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available.

US OSHA HAZARDOUS COMPONENTS (29 CFR 1910.1200) (Table Z-1 Limits for Air Contaminants):		
Substance	PEL-TWA (8 hour)	PEL-STEL (15 min)
Citric Acid	None known	None known

US ACGIH Threshold Limit Values		
Substance	TLV-TWA (8 hour)	TLV-STEL (15 min)
Citric Acid	None known	None known



## Safety Data Sheet CHAMBER BRITE

OSHA Hazard Communication Standard  
29 CFR 1910.1200. Prepared to GHS Rev 3 and  
Hazardous Products Regulations (WHMIS 2015)  
Prepared to GHS Rev 5.

Date of issue: 11.20.2016  
Page: 7/13

Canada. Alberta, Occupational Health and Safety Code		
Substance	TWA (8 hour)	STEL (15 min)
Citric Acid	None known	None known

Canada. British Columbia Occupational Exposure Limits		
Substance	TWA (8 hour)	STEL (15 min)
Citric Acid	None known	None known

Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.		
Substance	TWA (8 hour)	STEL (15 min)
Citric Acid	None known	None known

Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants		
	TWAEV (8 hour)	STEV (15 min)
Citric Acid	None known	None known

**Appropriate engineering controls:** Use process enclosures, local exhaust ventilation, or others engineering controls to keep airborne levels below recommend exposure limits. Ensure that eyewash stations and safety showers are proximal to the work-station location. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Individual protection measures, such as personal protective equipment:**

**Eye/face protection:** Wear safety glasses for eye protection that are tested and approved under appropriate government standards such as NIOSH (US).





## Safety Data Sheet CHAMBER BRITE

OSHA Hazard Communication Standard  
29 CFR 1910.1200. Prepared to GHS Rev 3 and  
Hazardous Products Regulations (WHMIS 2015)  
Prepared to GHS Rev 5.

Date of issue: 11.20.2016  
Page: 8/13

**Skin and hand protection:** Wear suitable protective clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

**Respiratory protection:** In case of insufficient ventilation, wear suitable respiratory equipment. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US).

**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.

### SECTION 9: Physical and chemical properties

#### Appearance (physical state, color, etc.):

Physical state:	Solid (Crystalline Powder).
Color:	White
Odor:	Odorless
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	150°C
Initial boiling point and boiling range:	Decomposes
Flash point:	155°C
Evaporation rate:	No data available
Flammability (solid, gas):	No data available.
<b>Upper/lower flammability or explosive limits</b>	
Flammability limit – lower %):	Not applicable
Flammability limit – upper (%):	Not applicable
Explosive limit – lower (%):	Not applicable
Explosive limit – upper (%):	Not applicable
Vapor pressure:	No data available
Vapor density:	No data available
Relative density:	No data available



## Safety Data Sheet CHAMBER BRITE

OSHA Hazard Communication Standard  
29 CFR 1910.1200. Prepared to GHS Rev 3 and  
Hazardous Products Regulations (WHMIS 2015)  
Prepared to GHS Rev 5.

Date of issue: 11.20.2016  
Page: 9/13

**Solubility (ies):** Soluble in cold water, hot water.  
**Partition coefficient (n-octanol/water):** -1.7  
**Auto-ignition temperature:** 1010°C (1850°F)  
**Decomposition temperature:** No data available  
**Viscosity (dynamic):** No data available

### SECTION 10: Stability and reactivity

**Reactivity:** No specific test data related to reactivity available for this product.  
**Chemical stability:** Stable under normal ambient and anticipated conditions of use.  
**Possibility of hazardous reactions:** Hazardous reactions not anticipated under normal temperature and pressures.  
**Conditions to avoid:** Extremes of temperature and direct sunlight.  
**Incompatible materials:** Materials to avoid include; Oxidizing agents, Bases, Reducing agents, Nitrates. Heavy metals. Non-corrosive in presence of glass.  
**Hazardous decomposition Products:** Carbon oxides.

### SECTION 11: Toxicological information

#### Information on likely routes of exposure:

**Inhalation:** Not expected to be a route of entry.  
**Ingestion:** Expected to be a route of entry.  
**Skin:** Expected to be a route of entry.  
**Eyes:** Expected to be a route of entry.

**Target Organs:** Eyes.

**Symptoms related to the physical, chemical, and toxicological characteristics:**  
May cause eye irritation.

**Delayed and immediate effects and chronic effects from short or long-term exposure:**  
None known.



## Safety Data Sheet CHAMBER BRITE

OSHA Hazard Communication Standard  
29 CFR 1910.1200. Prepared to GHS Rev 3 and  
Hazardous Products Regulations (WHMIS 2015)  
Prepared to GHS Rev 5.

Date of issue: 11.20.2016  
Page: 10/13

**Numerical measures of toxicity (such as acute toxicity estimates):**

### **Ingredient Information:**

Substance	Test Type (species)	Value
Citric Acid	LD <sub>50</sub> Oral (Rat)	5400 mg/kg
	LD <sub>50</sub> Dermal (Rabbit)	>2000 mg/kg
	LC <sub>50</sub> Inhalation (Rat)	No data available
PRODUCT – Chamber Brite	LD <sub>50</sub> Oral (Rat)	3000 mg/kg
	LD <sub>50</sub> Dermal (Rat)	No data available
	LC <sub>50</sub> Inhalation (Rat)	No data available

<b>Skin corrosion/irritation:</b>	Not expected to cause skin corrosion or irritation.
<b>Serious eye damage/eye irritation:</b>	Causes eye irritation and tissue damage on mucous membranes.
<b>Respiratory sensitization:</b>	Not expected to cause respiratory sensitization.
<b>Skin sensitization:</b>	Not expected to cause skin sensitization.
<b>Germ cell mutagenicity:</b>	Not expected to cause germ cell mutagenicity.
<b>Carcinogenicity:</b>	Not listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA.
<b>Reproductive toxicity:</b>	Not expected to cause reproductive toxicity.
<b>Specific target organ toxicity- Single exposure:</b>	This material is not expected to cause damage to organs from a single exposure.
<b>Specific target organ toxicity- Repeat exposure:</b>	May cause damage to the following organs: teeth.
<b>Aspiration hazard:</b>	This product is not anticipated to be an aspiration hazard.





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29 CFR 1910.1200. Prepared to GHS Rev 3 and  
Hazardous Products Regulations (WHMIS 2015)  
Prepared to GHS Rev 5.

Date of issue: 11.20.2016  
Page: 11/13

### SECTION 12: Ecological information

**Ecotoxicity (aquatic and terrestrial, where available):**

**Product data:** No data available

**Ingredient Information:**

Substance	Test Type	Species	Value
Citric acid	LC <sub>50</sub>	Fish Leuciscus idus melanotus	440 mg/l 48 hours
	EC <sub>50</sub>	Daphnia magna	1.535 mg/l 24 hours
	EC <sub>50</sub>	Algae	No data available

**Persistence and Degradability:** Not established.

**Bioaccumulative Potential:** Not established

**Mobility in Soil:** Not established.

**Other adverse effects (such as hazardous to the ozone layer):** Not established.

### SECTION 13: Disposal considerations

**Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.**

**Product** - Must not be disposed together with household garbage. Do not allow product to reach sewage system. Dispose of waste materials in accordance with applicable local and national laws and regulations.

**Contaminated packaging** - Since emptied containers retain product residue, follow label warnings even after container is emptied. Dispose of as unused product.

### SECTION 14: Transport Information

**US Department of Transportation Classification (49CFR)**

Not regulated by DOT.



## Safety Data Sheet CHAMBER BRITE

OSHA Hazard Communication Standard  
29 CFR 1910.1200. Prepared to GHS Rev 3 and  
Hazardous Products Regulations (WHMIS 2015)  
Prepared to GHS Rev 5.

Date of issue: 11.20.2016  
Page: 12/13

### IMDG (Transport by sea)

Not regulated by IMDG.

### IATA (Transport by air)

Not regulated by IATA.

### Canada TDG Transportation of Dangerous Goods Regulations (SOR/2001-286)

Not regulated by TDG.

### Environmental hazards

Marine pollutant: No

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

No further relevant information available.

### Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises.

None known

## SECTION 15: Regulatory Information

### USA:

**United States Federal Regulations:** This SDS complies with the OSHA, 29 CFR 1910.1200.

**Toxic Substances Control Act (TSCA)** – All of the ingredients are listed/registered or exempted on the U.S. EPA TSCA Inventory List.

**CERCLA RQ:** None listed

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### Hazard categories:

Acute (Immediate) Health Hazard - Yes

Chronic (Delayed) Health Hazard - No

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard – No

**Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):** None listed



## Safety Data Sheet CHAMBER BRITE

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29 CFR 1910.1200. Prepared to GHS Rev 3 and  
Hazardous Products Regulations (WHMIS 2015)  
Prepared to GHS Rev 5.

Date of issue: 11.20.2016  
Page: 13/13

**Section 311 hazardous chemical:** None listed

**SARA Section 313 (Specific toxic chemical listings):** None listed

### STATE REGULATIONS:

This SDS contains specific health and safety data is applicable for state requirements. For details on your regulatory requirements you should contact the appropriate agency in your state.

**California Proposition 65 (California Safe Drinking Water and Toxic Enforcement Act of 1986:**  
No components are listed on Prop 65.

**Massachusetts Right to Know:** None of the components are listed on the Massachusetts Right to Know List.

**New Jersey Right to Know:** Citric acid is listed on the New Jersey Right to Know list.

**Pennsylvania Right to Know:** Citric acid is listed on the Pennsylvania Right to Know List.

### WHMIS Classification

Class D2B      Toxic Material Causing Other Toxic Effects      Moderate eye irritant

### SECTION 16: Other Information

Revision Date: November 20<sup>th</sup> 2016

#### DISCLAIMER:

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





## Safety Data Sheet

**Trade name:** CIDEX® OPA Solution

**Product no.:** SDS-0010006E

**Current version :** 1.2.1, issued: 04.02.2015

**Replaced version:** 1.2.0 issued: 05.03.2013

**Region:** USA

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

#### 1.1 Product identifier

**Trade name**

**CIDEX® OPA Solution**

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

**Relevant identified uses of the substance or mixture**

High level disinfection

#### 1.3 Details of the supplier of the safety data sheet

**Address**

Advanced Sterilization Products

33 Technology Drive

Irvine, CA 92618

Telephone no. (800) 755-5900

#### 1.4 Emergency telephone number

(703) 527-3887

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification in accordance with Regulation (EC) No 1272/2008**

Not a dangerous mixture according to GHS

#### 2.2 Label elements

**Labeling (EC) No 1272/2008:**

Not a dangerous mixture according to GHS

**Signal word**

-

**Hazard statements**

EUH208

Contains ortho-phthalaldehyde. May produce an allergic reaction.

EUH210

Safety data sheet available on request.

**Precautionary statements**

P103

Read label before use

#### 2.3 Other hazards

PBT assessment

The product is not considered to be a PBT.

vPvB assessment

The product is not considered to be a vPvB.

### SECTION 3: Composition/information on ingredients

#### 3.1 Substances

Not applicable. The product is not a substance.

#### 3.2 Mixtures

**Chemical characterization**

aqueous solution



# Safety Data Sheet

**Trade name:** CIDEX® OPA Solution




**Product no.:** SDS-0010006E

**Current version :** 1.2.1, issued: 04.02.2015

**Replaced version:** 1.2.0 issued: 05.03.2013

**Region:** USA

## Hazardous ingredients

No	Substance name CAS / EC / REACH no	Classification 67/548/EEC	Concentration	%-b.w.
1	phthalaldehyde 643-79-8 211-402-2 -	   Acute toxicity, Oral (Category 3) H301 Skin corrosion (Category 1B) H314 Skin sensitization (Category 1) H317 Acute aquatic toxicity (Category 1) H400	< 1,0	%-b.w.

Full text for all notes: pls. see section 16

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General information

In case of persisting adverse effects, consult a physician. Change contaminated, saturated clothing.

#### After inhalation

Remove affected person from the immediate area. Ensure supply of fresh air. In case of persisting adverse effects consult a physician.

#### After skin contact

Wash off immediately with soap and water.

#### After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an ophthalmologist.

#### After ingestion

Summon a doctor immediately and show label or packaging. Rinse out mouth and give plenty of water or milk to drink. Do not induce vomiting. Never give anything by mouth to an unconscious person.

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

#### Symptoms

Allergic symptoms

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

No data available.

#### Unsuitable extinguishing media

No data available.

### 5.2 Special hazards arising from the substance or mixture

None known

### 5.3 Advice for firefighters

Product itself does not burn. Adapt extinguisher and fire-fighting measures to fire in the environment. Cool endangered containers with water spray jet.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Refer to protective measures listed in sections 7 and 8.



# Safety Data Sheet

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**Region:** USA

## For emergency responders

No data available. Personal protective equipment (PPE) - see Section 8.

## 6.2 Environmental precautions

Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

## 6.3 Methods and material for containment and cleaning up

Pick up with absorbent material (e.g., sand, sawdust, general-purpose binder). When picked up, treat material as prescribed under heading "Disposal considerations".

## 6.4 Reference to other sections

Observe protective measures in sections 7 and 8.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

#### Advice on safe handling

Avoid contact with skin and eyes. Open and handle container with care.

#### General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Wash hands before breaks and after work. Provide eye wash fountain in work area. Do not inhale vapours.

#### Advice on protection against fire and explosion

No special measures necessary.

### 7.2 Conditions for safe storage, including any incompatibilities

#### Technical measures and storage conditions

Keep container tightly closed, cool and dry. Protect from atmospheric moisture and water.

#### Recommended storage temperature

Value < 50 °C

#### Requirements for storage rooms and vessels

Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Appropriate Material steel; stainless steel; aluminium; PVC; polyethylene

#### Advice on storage assembly

Do not store together with: Acids; Alkalies; Reducing agents; Oxidizing agents

### 7.3 Specific end use(s)

No data available.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

No parameters available for monitoring.

### 8.2 Exposure controls

#### Appropriate engineering controls

No data available.

#### Personal protective equipment

##### Respiratory protection

If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of aerosol and mist formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

##### Eye / face protection

Safety glasses with side protection shield (EN 166)

##### Hand protection

In case of intensive contact, wear protective gloves (EN 374). Check in any case suitability of protective glove for the specific workplace conditions (e.g. mechanical resistance, product compatibility, antistatic properties). The glove manufacturer's instructions and information regarding storage, care and replacement.

Appropriate Material nitrile

Appropriate Material PVC



## Safety Data Sheet

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**Region:** USA

**Other**

Normal chemical work clothing.

**Environmental exposure controls**

No data available.

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

**Form/Colour**

liquid  
light blue; clear

**Odour**

mild characteristic "antiseptic" odour

**Odour threshold**

No data available

**pH value**

Value	7,2	-	7,8
Remarks	neutral		

**Boiling point / boiling range**

Value	100	°C
-------	-----	----

**Melting point / melting range**

No data available

**Setting point / solidification range**

Value	0	°C
-------	---	----

**Decomposition point / decomposition range**

No data available

**Flash point**

Not applicable

**Auto-ignition temperature**

No data available

**Oxidising properties**

No data available

**Explosive properties**

No data available

**Flammability (solid, gas)**

No data available

**Lower flammability or explosive limits**

No data available

**Upper flammability or explosive limits**

No data available

**Vapour pressure**

No data available

**Vapour density**

No data available

**Evaporation rate**

No data available

**Relative density**

No data available

**Density**

Value	1,0	g/ml
Reference temperature	20	°C





## Safety Data Sheet

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**Replaced version:** 1.2.0 issued: 05.03.2013

**Region:** USA

### Solubility in water

Remarks soluble

### Solubility(ies)

No data available

### Partition coefficient: n-octanol/water

No data available

### Viscosity

No data available

## 9.2 Other information

### Other information

No data available.

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No data available.

### 10.2 Chemical stability

No data available.

### 10.3 Possibility of hazardous reactions

No data available.

### 10.4 Conditions to avoid

Temperatures > 50°C.

### 10.5 Incompatible materials

Acids; Alkalies; Reducing agents; Oxidizing agents; Water

### 10.6 Hazardous decomposition products

No hazardous decomposition products known.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute oral toxicity

LD50 > 5000 mg/kg

Species

rat

Source

Manufacturer

#### Acute dermal toxicity

Remarks No data available.

#### Acute inhalational toxicity

Remarks No data available.

#### Skin corrosion/irritation

Source

Manufacturer

Evaluation

slightly irritant

#### Serious eye damage/irritation

Source

Manufacturer

Evaluation

slightly irritant

#### Respiratory or skin sensitisation

Route of exposure

Skin

Remarks

Allergic skin reaction possible in case of repeated or prolonged contact.

#### Germ cell mutagenicity

No data available



## Safety Data Sheet

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**Region:** USA

### Reproduction toxicity

No data available

### Carcinogenicity

No data available

### STOT-single exposure

No data available

### STOT-repeated exposure

No data available

### Aspiration hazard

No data available

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

Product contact may lead to sensitisation with sensitive persons.

### Other information

Exercise customary precautions when handling chemicals.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Fish toxicity

No data available

#### Daphnia toxicity

No data available

#### Algae toxicity

No data available

#### Bacteria toxicity

No data available

### 12.2 Persistence and degradability

No data available.

### 12.3 Bioaccumulative potential

No data available.

### 12.4 Mobility in soil

No data available.

### 12.5 Results of PBT and vPvB assessment

#### Results of PBT and vPvB assessment

PBT assessment

The product is not considered to be a PBT.

vPvB assessment

The product is not considered to be a vPvB.

### 12.6 Other adverse effects

No data available.

### 12.7 Other information

#### Other information

The active component ortho-phthalaldehyde is classified as toxic (Category 1) to aquatic organisms and is not considered readily biodegradable.

Do not discharge product unmonitored into the environment.



## Safety Data Sheet

**Trade name:** CIDEX® OPA Solution

**Product no.:** SDS-0010006E

**Current version :** 1.2.1, issued: 04.02.2015

**Replaced version:** 1.2.0 issued: 05.03.2013

**Region:** USA

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

##### Product

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

##### Packaging

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

### SECTION 14: Transport information

#### 14.1 Transport ADR/RID/ADN

The product is not subject to ADR/RID/ADN regulations.

#### 14.2 Transport IMDG

The product is not subject to IMDG regulations.

#### 14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

#### 14.4 Other information

No data available.

#### 14.6 Special precautions for user

No data available.

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

Not relevant

### SECTION 15: Regulatory information

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

##### EU regulations

**Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances**

Remarks

Annex I, part 1 + 2: not mentioned. With regard to possibly appropriate decomposition products see Chapter 10.

#### 15.2 Chemical safety assessment

No data available.



## Safety Data Sheet

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**Current version :** 1.2.1, issued: 04.02.2015

**Replaced version:** 1.2.0 issued: 05.03.2013

**Region:** USA

### SECTION 16: Other information

Changes made since the last version

**Sources of key data used to compile the data sheet:**

EC Directive 67/548/EC resp. 99/45/EC as amended in each case.

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EC

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

**Full text of the H- and EUH- phrases drawn up in sections 2 and 3 (provided not already drawn up in these sections)**

H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.

**Department issuing safety data sheet**

Ingenieur- und Sachverständigenbüro ROLAND BRAUN

Peter-Timm-Straße 21, D-22457 Hamburg

Tel.: +49 40 / 43 27 09 15 Fax: +49 40 / 43 27 09 16 e-mail: [info@rolandbraun.de](mailto:info@rolandbraun.de)

This information is based on our present state of knowledge. The security data sheet describes products with a view to the security requirements. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.

(2012 OSHA Hazard Communication Standard (29 CFR 1910.1200))

**SAFETY DATA SHEET****SIEMENS**

Clinitek Atlas Control Strips for Urine Chemistry

SDS # :

5019

**Section 1. Identification**

**Product identifier** : Clinitek Atlas Control Strips for Urine Chemistry  
**Product code** : 5019, 5037, 09204200, 03922594, 10311124, 10311135  
**Product type** : Solid.

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

Not applicable.

**Manufactured/supplied** : Siemens Healthcare Diagnostics Inc.  
 511 Benedict Avenue  
 Tarrytown, NY 10591-5097 USA  
 1-877-229-3711  
 (800) 424-9300 (CHEMTREC) (24/365)

**Section 2. Hazards identification**

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

**Classification of the substance or mixture** : Not classified.

**Additional information** : Not available.  
 Not available.

**GHS label elements**

**Signal word** : No signal word.

**Hazard statements** : No known significant effects or critical hazards.

**Precautionary statements**

**Prevention** : Not applicable.

**Response** : Not applicable.

**Storage** : Not applicable.

**Disposal** : Not applicable.

**Hazards not otherwise classified** : None known.

**Section 3. Composition/information on ingredients**

**Substance/mixture** : Mixture

Ingredient name	%	CAS number
sodium carbonate	2	497-19-8

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** : In case of fire, use water spray (fog), foam or dry chemical.
- Unsuitable extinguishing media** : None known.

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

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:  
carbon dioxide  
carbon monoxide  
halogenated compounds  
metal oxide/oxides

- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

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

## Section 5. Fire-fighting measures

## 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 spilled material. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

### Methods and materials for containment and cleaning up

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

## 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 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. 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

## Section 8. Exposure controls/personal protection

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

## Section 9. Physical and chemical properties

- Physical state** : Solid.
- Color** : White.
- Odor** : Odorless.
- pH** : Not applicable.
- Flash point** : Not available.
- Flammability (solid, gas)** : Not relevant/applicable due to nature of the product.
- Relative density** : Not relevant/applicable due to nature of the product.
- Solubility in water** : Not relevant/applicable due to nature of the product.
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition 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** : No specific data.
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.



## Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
sodium carbonate	LD50 Oral	Rat	4090 mg/kg	-

#### Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
sodium carbonate	Eyes - Mild irritant	Rabbit	-	0.5 minutes	-
	Eyes - Moderate irritant	Rabbit	-	100 milligrams	-
	Eyes - Severe irritant	Rabbit	-	24 hours 100 milligrams	-
	Skin - Mild irritant	Rabbit	-	50 milligrams	-
		Rabbit	-	24 hours 500 milligrams	-

#### Sensitization

Not available.

#### Mutagenicity

Not available.

#### Carcinogenicity

Not available.

#### Reproductive toxicity

Not available.

#### Teratogenicity

Not available.

#### Specific target organ toxicity (single exposure)

Not available.

#### Specific target organ toxicity (repeated exposure)

Not available.

#### Aspiration hazard

Not available.

**Information on the likely routes of exposure** : Not available.

#### Potential acute health effects

**Eye contact** : 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

## Section 11. Toxicological information

**Potential immediate effects** : Not available.

**Potential delayed effects** : Not available.

### Long term exposure

**Potential immediate effects** : Not available.

**Potential delayed effects** : Not available.

### Potential chronic health effects

Not available.

**General** : No known significant effects or critical hazards.

**Carcinogenicity** : No known significant effects or critical hazards.

**Mutagenicity** : No known significant effects or critical hazards.

**Teratogenicity** : No known significant effects or critical hazards.

**Developmental effects** : No known significant effects or critical hazards.

**Fertility effects** : No known significant effects or critical hazards.

### Numerical measures of toxicity

#### Acute toxicity estimates

Route	ATE value
Oral	95329.1 mg/kg

## Section 12. Ecological information

### Toxicity

Product/ingredient name	Result	Species	Exposure
sodium carbonate	Acute EC50 242000 µg/l Fresh water	Algae - Navicula seminulum	96 hours
	Acute LC50 176000 µg/l Fresh water	Crustaceans - Amphipoda	48 hours
	Acute LC50 265000 µg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 300000 µg/l Fresh water	Fish - Lepomis macrochirus	96 hours

### Persistence and degradability

Not available.

### Bioaccumulative potential

Not available.

### Mobility in soil

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

## Section 14. Transport information

### DOT Classification

**UN number** Not regulated.

**UN proper shipping name** -

**Transport hazard class(es)** -

**Packing group** -

**Environmental hazards** No.

**Additional information** -

### TDG Classification

**UN number** Not regulated.

**UN proper shipping name** -

**Transport hazard class(es)** -

**Packing group** -

**Environmental hazards** No.

**Additional information** -

### ADR/RID

**UN number** Not regulated.

**UN proper shipping name** -

**Transport hazard class(es)** -

## Section 14. Transport information

**Packing group** -

**Environmental hazards** No.

**Additional information** -

### IMDG

**UN number** Not regulated.

**UN proper shipping name** -

**Transport hazard class(es)** -

**Packing group** -

**Environmental hazards** No.

**Additional information** -

### IATA

**UN number** Not regulated.

**UN proper shipping name** -

**Transport hazard class(es)** -

**Packing group** -

**Environmental hazards** No.

**Additional information** -

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

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

## Section 15. Regulatory information

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

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

**Clean Air Act Section 602 Class I Substances** : Not listed

**Clean Air Act Section 602 Class II Substances** : Not listed

**DEA List I Chemicals (Precursor Chemicals)** : Not listed

**DEA List II Chemicals (Essential Chemicals)** : Not listed

### SARA 302/304

#### Composition/information on ingredients

No products were found.

**SARA 304 RQ** : Not applicable.

### SARA 311/312

**Classification** : Not applicable.

#### Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
sodium carbonate	2	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.

### International regulations

**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

**Date of issue/Date of revision** : 5/12/2017

**Version** : 1.05

## Section 16. Other information

### Key to abbreviations

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

▣ Indicates information that has changed from previously issued version.

### Notice to reader

### Allergen

:



# SAFETY DATA SHEET

**Issuing Date** January 5, 2015

**Revision Date** New

**Revision Number** 0

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

### Product identifier

**Product Name** Clorox® Broad Spectrum Quaternary Disinfectant Cleaner

### Other means of identification

**EPA Registration Number** 67619-20

### Recommended use of the chemical and restrictions on use

**Recommended Use** Multi-purpose spray cleaner and disinfectant

**Uses advised against** No information available

### Details of the supplier of the safety data sheet

#### **Supplier Address**

Clorox Professional Products Company  
1221 Broadway  
Oakland, CA 94612

Phone: 1-510-271-7000

### Emergency telephone number

#### **Emergency Phone Numbers**

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

## 2. HAZARDS IDENTIFICATION

### Classification

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

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

### GHS Label elements, including precautionary statements

#### Emergency Overview

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

### Precautionary Statements - Prevention

Wash hands thoroughly after handling.

### Precautionary Statements - Response

If skin irritation occurs: Get medical advice.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention

### Precautionary Statements - Storage

None

### Precautionary Statements - Disposal

None

### Hazards not otherwise classified (HNOC)

Not applicable

### Unknown Toxicity

Not applicable.

### Other information

Harmful to aquatic life with long lasting effects.

### Interactions with Other Chemicals

None known.



### 3. COMPOSITION/INFORMATION ON INGREDIENTS

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

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

### 4. FIRST AID MEASURES

#### First aid measures

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

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

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

#### Indication of any immediate medical attention and special treatment needed

**Notes to Physician** Treat symptomatically.

### 5. FIRE-FIGHTING MEASURES

#### Suitable Extinguishing Media

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

#### Unsuitable Extinguishing Media

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

#### Specific Hazards Arising from the Chemical

No information available

#### Explosion Data

**Sensitivity to Mechanical Impact** None

**Sensitivity to Static Discharge** None

#### Protective Equipment and Precautions for Firefighters

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

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

<b>Personal Precautions</b>	Avoid contact with eyes and skin.
<b>Other Information</b>	Refer to protective measures listed in Sections 7 and 8.

### Environmental precautions

<b>Environmental Precautions</b>	See Section 12 for additional ecological Information
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### Methods and material for containment and cleaning up

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

## 7. HANDLING AND STORAGE

### Precautions for safe handling

<b>Handling</b>	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes, skin, and clothing. Do not eat, drink, or smoke when using this product.
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### Conditions for safe storage, including any incompatibilities

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

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### Exposure Guidelines

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

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

### Appropriate engineering controls

<b>Engineering Measures</b>	Showers Eyewash stations Ventilation systems
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**Individual protection measures, such as personal protective equipment**

<b>Eye/Face Protection</b>	If splashes are likely to occur, wear safety glasses with side-shields. None required for consumer use.
<b>Skin and Body Protection</b>	Wear rubber or neoprene gloves for sensitive skin or if there is the potential for repeated or prolonged skin contact.
<b>Respiratory Protection</b>	If irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
<b>Hygiene Measures</b>	Remove and wash contaminated clothing before re-use. Avoid contact with skin, eyes, or clothing. Do not eat, drink, or smoke when using this product.

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

<b>Physical State</b>	Thin liquid		
<b>Appearance</b>	Clear	<b>Odor</b>	Slight solvent
<b>Color</b>	Colorless	<b>Odor Threshold</b>	No information available

<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks/ Method</u></b>
pH	12 - 12.5	None known
Melting/freezing point	No data available	None known
Boiling Point/Range	No data available	None known
Flash Point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
Upper flammability limit	No data available	None known
Lower flammability limit	No data available	None known
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Specific Gravity	~1.0	None known
Water Solubility	Soluble in water.	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive Properties	Not explosive	
Oxidizing Properties	No data available	

**Other Information**

<b>Softening Point</b>	No data available
<b>VOC Content (%)</b>	No data available
<b>Particle Size</b>	No data available
<b>Particle Size Distribution</b>	No data available

## 10. STABILITY AND REACTIVITY

### Reactivity

No data available.

### Chemical stability

Stable under recommended storage conditions.

### Possibility of Hazardous Reactions

None under normal processing.

### Conditions to avoid

None known.

### Incompatible materials

None known.

### Hazardous Decomposition Products

None known based on information supplied.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	Exposure to vapor or mist may irritate respiratory tract.
<b>Eye Contact</b>	May cause eye irritation.
<b>Skin Contact</b>	Prolonged contact may cause irritation.
<b>Ingestion</b>	Ingestion may cause irritation to mucous membranes and gastrointestinal irritation, nausea, vomiting, and diarrhea.

#### Component Information

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

### Information on toxicological effects

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

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

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

**Aspiration Hazard** No information available.

**Numerical measures of toxicity Product Information**

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

**ATEmix (oral)**

17.5 g/kg

**ATEmix (dermal)**

33.8 g/kg

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

Harmful to aquatic life with long lasting effects.

**Persistence and Degradability**

No information available.

**Bioaccumulation**

No information available.

**Other Adverse Effects**

No information available.

## 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

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

**Contaminated Packaging**

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

## 14. TRANSPORT INFORMATION

**DOT** Not regulated

**TDG** Not regulated

**ICAO** Not regulated

**IATA** Not regulated

**IMDG/IMO** Not regulated

## 15. REGULATORY INFORMATION

**Chemical Inventories**

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

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

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

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

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

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

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

**SARA 311/312 Hazard Categories**

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

**Clean Water Act**

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

**CERCLA**

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

**EPA Statement**

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

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

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

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations**

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

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

D2B Toxic Materials



<b>16. OTHER INFORMATION</b>
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<b><u>NFPA</u></b>	Health Hazard 1	Flammability 0	Instability 0	Physical and Chemical Hazards -
<b><u>HMIS</u></b>	Health Hazard 1	Flammability 0	Physical Hazard 0	Personal Protection B

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

**General Disclaimer**

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

**End of Safety Data Sheet**







MSDS DATE: 01/13/2015

### \*\*\*MATERIAL SAFETY DATA SHEET\*\*\*

#### SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

**PRODUCT NAME:** CONSULT® Strep A Test  
**REORDER #:** 4999 (50T/Kit); 5003 (25T/Kit)

**DISTRIBUTED BY:** McKesson Medical-Surgical Inc.  
 8741 Landmark Road  
 Richmond, VA 23228

**INFORMATION LINE:** 1-800-777-4908

**EMERGENCY PHONE:** 1-800-424-9300 (CHEMTREC)

**PRODUCT DESCRIPTION:** In vitro diagnostic medical device. Test strip impregnated with dried chemical / biochemical reagents. For professional use only.

#### SECTION 2: COMPOSITION/INFORMATION OF INGREDIENTS

INGREDIENT	CAS NO.	EINECS NO.	CLASSIFICATION	CONCENTRATION %
Tris (hydroxymethyl) aminomethane	77-86-2	201-064-4	Xi, R 36/37/38	10—20%
Sodium Carbonate	497-19-8	207-838-8	Xi, R 36	5—10%

**SECTION 2 NOTES:** As an article, the device is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200. Each device is packaged in a foil pouch.

#### SECTION 3: HAZARDS IDENTIFICATION

**ROUTES OF ENTRY:** Eye contact, skin contact

##### POTENTIAL HEALTH EFFECTS

**EYES:** Irritating effect following contact with the chemicals impregnated in the test

strip. **SKIN:** Contact with the chemicals impregnated in the test strip may cause

mild irritation **INGESTION:** N/A

**INHALATION:** N/A

**ACUTE HEALTH HAZARDS:** N/A

**CHRONIC HEALTH HAZARDS:** N/A

**MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE:** N/A

##### CARCINOGENICITY

**OSHA:** N/A

**ACGIH:** N/A

**NTP:** N/A

**IARC:** N/A

**OTHER:** N/A

**SECTION 3 NOTES:** N/A

#### SECTION 4: FIRST-AID MEASURES

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.



MSDS DATE: 01/13/2015

**EYES:** Immediately rinse opened eye for several minutes under running water. Seek medical advice.

**SKIN:** Wash with soap and water and rinse thoroughly. Consult a doctor if irritation persists.

**INGESTION:** If desiccant or other components are swallowed, seek medical attention.

**INHALATION:** N/A

**NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:** N/A

**SECTION 4 NOTES:** N/A

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#### SECTION 5: FIRE-FIGHTING MEASURES

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

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

**AUTOIGNITION TEMPERATURE:** Not self-igniting

**NFPA HAZARD CLASSIFICATION**

<b>HEALTH:</b> N/A	<b>FLAMMABILITY:</b> N/A	<b>REACTIVITY:</b> N/A
<b>OTHER:</b> N/A		

**HMIS HAZARD CLASSIFICATION**

<b>HEALTH:</b> N/A	<b>FLAMMABILITY:</b> N/A	<b>REACTIVITY:</b> N/A
<b>PROTECTION:</b> N/A		

**EXTINGUISHING MEDIA:** CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire-extinguishing methods suitable to surrounding conditions.

**SPECIAL FIRE FIGHTING PROCEDURES:** Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

**UNUSUAL FIRE AND EXPLOSION HAZARDS:** The device contains combustible materials. Product does not present an explosion hazard.

**HAZARDOUS DECOMPOSITION PRODUCTS:** In case of fire, the following may be released: hazardous fumes and vapors, carbon oxides and nitrogen oxides.

**SECTION 5 NOTES:**

---

#### SECTION 6: ACCIDENTAL RELEASE MEASURES

---

**ACCIDENTAL RELEASE MEASURES:** Collect material and dispose of as waste according to Section 13. Avoid release to the environment.

**SECTION 6 NOTES:** Refer to Section 8 for protective measures when handling the spillage.

---

#### SECTION 7: HANDLING AND STORAGE

---

**HANDLING:** N/A



**MSDS DATE:** 01/13/2015

**STORAGE:** Store in the original container at 2—30°C

**OTHER PRECAUTIONS:** Keep out of reach of children

**SECTION 7 NOTES:** N/A

---

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

---

### ENGINEERING

#### CONTROLS:

**VENTILATION:** N/A

**RESPIRATORY PROTECTION:** Not required

**EYE PROTECTION:** Not required

**SKIN PROTECTION:** Latex/natural rubber disposable gloves (for sample handling); Lab coat

**OTHER PROTECTIVE CLOTHING OR EQUIPMENT:** N/A

**WORK HYGIENIC PRACTICES:** Specimens should be handled as potentially infectious materials. Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.

**EXPOSURE GUIDELINES:** The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

**SECTION 8 NOTES:** N/A

---

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

---

**APPEARANCE & ODOR:** Laminated test strip; odorless

**PHYSICAL STATE:** The device is an article containing solid components

**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 (H<sub>2</sub>O = 1):** N/A

@ N/A

**EVAPORATION RATE:**

N/A **BASIS (=1):** N/A

**SOLUBILITY IN WATER:**

N/A

**PERCENT SOLIDS BY WEIGHT:** N/A



MSDS DATE: 01/13/2015

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): None

INCOMPATIBILITY (MATERIAL TO AVOID): None

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: No dangerous decomposition product known

HAZARDOUS POLYMERIZATION: N/A

CONDITIONS TO AVOID (POLYMERIZATION):

N/A SECTION 10 NOTES: N/A

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#### SECTION 11: TOXICOLOGICAL INFORMATION

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**TOXICOLOGICAL INFORMATION:** Quantitative data on the toxic effects of this product is not available; No sensitizing effects known

SECTION 11 NOTES: N/A

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#### SECTION 12: ECOLOGICAL INFORMATION

---

**ECOLOGICAL INFORMATION:** Quantitative data on the toxic effects of this product is not available. The device contains plastic and other components that are not readily degradable.

SECTION 12 NOTES: N/A

---

#### SECTION 13: DISPOSAL CONSIDERATIONS

---

**WASTE DISPOSAL METHOD:** Used devices and other contaminated materials should be disposed of as potentially bio-hazardous waste. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact relevant (local) authorities and/or an approved waste-disposal company for information. Disposal must be made in accordance with local waste



MSDS DATE: 01/13/2015

management regulations. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

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:** Not regulated for transport

---

**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

**SECTION 15 NOTES:** N/A

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**SECTION 16: OTHER INFORMATION**

---

**OTHER INFORMATION:** Labeling according to EU guidelines: Code letter and hazard designation of product: Xi (Irritant)



**MSDS DATE:** 01/13/2015

**RISK PHRASES:** 36 Irritating to Eyes

**SAFETY PHRASES:** S2 Keep out of reach of children; 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice; 46 If swallowed, seek medical advice immediately and show this container or label; 60 This material and its container must be disposed of as hazardous waste.

**PREPARATION INFORMATION:** The preparation is exempt from the above labeling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

**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.



## Cyanocobalamin Injection, USP

### Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations  
Revision Date: 11/12/2015 Date of issue: 11/12/2015

Version: 1.0

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Solution

**Product Name:** Cyanocobalamin Injection, USP

**Product Code:** 0517-0031-25; 0517-0032-25; 0517-0130-05

### 1.2. Intended Use of the Product

**Use of the substance/mixture:** Cyanocobalamin is indicated for vitamin B12 deficiencies due to malabsorption which may be associated with the following conditions: Addisonian (pernicious) anemia; gastrointestinal pathology, dysfunction, or surgery, including gluten enteropathy or sprue, small bowel bacterial overgrowth, total or partial gastrectomy; fish tapeworm infestation; malignancy of pancreas or bowel; folic acid deficiency.

### 1.3. Name, Address, and Telephone of the Responsible Party

#### Company

Luitpold Pharmaceuticals, Inc.

One Luitpold Drive

P.O. Box 9001

Shirley, NY 11967

1-800-645-1706

[www.luitpold.com](http://www.luitpold.com)

### 1.4. Emergency Telephone Number

**Emergency Number** : CHEMTREC 1-800-424-9300

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

#### Classification (GHS-US)

Not classified

### 2.2. Label Elements

#### GHS-US Labeling

No labeling applicable

### 2.3. Other Hazards

Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. May cause an allergic reaction in sensitive individuals. See package insert for additional information.

### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Water for Injection	(CAS No) 7732-18-5	97.5	Not classified
Benzyl alcohol	(CAS No) 100-51-6	1.5	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401
Sodium chloride	(CAS No) 7647-14-5	0.9	Not classified
Cyanocobalamin	(CAS No) 68-19-9	0.1	Not classified
Sodium hydroxide	(CAS No) 1310-73-2	Added to adjust pH	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

# Cyanocobalamin Injection, USP

## Safety Data Sheet

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

Hydrochloric acid	(CAS No) 7647-01-0	Added to adjust pH	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
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Full text of H-phrases: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First Aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical attention (show the label if possible).

**First-aid Measures After Inhalation:** Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty.

**First-aid Measures After Skin Contact:** Remove contaminated clothing and shoes. Flush with plenty of water for at least 15 minutes. Seek medical attention if irritation develops. Wash contaminated clothing before reuse.

**First-aid Measures After Eye Contact:** Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

**First-aid Measures After Ingestion:** Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER and doctor/physician.

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

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

**Symptoms/Injuries After Inhalation:** Overexposure may be irritating to the respiratory system.

**Symptoms/Injuries After Skin Contact:** Contact during a long period may cause slight irritation.

**Symptoms/Injuries After Eye Contact:** Direct contact with the eyes is likely irritating.

**Symptoms/Injuries After Ingestion:** Ingestion is likely to be harmful or have adverse effects. May cause gastrointestinal irritation, nausea, vomiting and diarrhea.

**Chronic Symptoms:** None expected under normal conditions of use.

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Use extinguishing media appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** None known.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Not considered flammable but may burn at high temperatures.

**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire. Under fire conditions, hazardous fumes will be present.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Other Information:** Refer to Section 9 for flammability properties.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid all contact with skin, eyes, or clothing. Avoid breathing (vapor, mist, spray).

#### 6.1.1. For Non-emergency Personnel

**Protective Equipment:** Use appropriate personal protection equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Responders

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Stop leak if safe to do so.

### 6.2. Environmental Precautions

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

### 6.3. Methods and Material for Containment and Cleaning Up

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



# Cyanocobalamin Injection, USP

## Safety Data Sheet

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

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Spills should be contained with mechanical barriers. Transfer spilled material to a suitable container for disposal. If spilled directly onto the ground, remove sufficient soil to ensure material is fully recovered.

### 6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** When handling pharmaceutical products, avoid all contact and inhalation of vapor, mist, spray. Do not mix with other drugs. This product contains benzyl alcohol as a preservative. Practice good housekeeping - spillage can be slippery on smooth surface either wet or dry.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Store in a dry, well ventilated place at 20° -25°C (68° - 77°F) away from incompatible materials. Protect from light.

**Incompatible Products:** Strong acids. Strong oxidizers.

### 7.3. Specific End Use(s) Pharmaceutical

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
USA IDLH	US IDLH (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

### 8.2. Exposure Controls

#### Appropriate Engineering Controls

- : Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.

#### Personal Protective Equipment

- : Protective goggles. Gloves. Protective clothing.



#### Materials for Protective Clothing

- : Not required for normal conditions of use.

#### Hand Protection

- : Protective gloves.

#### Eye Protection

- : In case of splash hazard: chemical goggles or safety glasses.

#### Skin and Body Protection

- : Wear suitable protective clothing.

#### Respiratory Protection

- : Use a NIOSH-approved respirator or self-contained breathing apparatus whenever exposure may exceed established Occupational Exposure Limits.

#### Environmental Exposure Controls

- : Do not allow the product to be released into the environment.

#### Consumer Exposure Controls

- : Do not eat, drink or smoke during use.

# Cyanocobalamin Injection, USP

## Safety Data Sheet

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

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear, dark red solution
Odor	: Odor of benzyl alcohol
Odor Threshold	: No data available
pH	: 4.5 - 7.0
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: Not flammable, Not combustible
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Specific Gravity	: ≈ 1.0
Solubility	: Water: Freely soluble
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

#### 9.2. Other Information

VOC content : 1.5 % (Benzyl alcohol used as a preservative)

### SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, high or low temperatures, and incompatible materials.
- 10.5. Incompatible Materials:** Strong oxidizers. Strong acids.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition generates : Carbon oxides (CO, CO<sub>2</sub>), Nitrogen oxides, Phosphorus oxides, Cobalt oxides.

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

<b>Benzyl alcohol (100-51-6)</b>	
LD50 Oral Rat	1230 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 4.178 mg/l/4h
ATE (Vapors)	11.00 mg/l/4h
ATE (Dust/Mist)	1.50 mg/l/4h
<b>Sodium chloride (7647-14-5)</b>	
LD50 Oral Rat	3 g/kg
LC50 Inhalation Rat	> 42 g/m <sup>3</sup> (Exposure time: 1 h)
<b>Sodium hydroxide (1310-73-2)</b>	
LD50 Dermal Rabbit	1350 mg/kg
<b>Hydrochloric acid (7647-01-0)</b>	
LD50 Oral Rat	238 - 277 mg/kg
LD50 Dermal Rabbit	> 5010 mg/kg
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h)
LC50 Inhalation Rat	1411 ppm

# Cyanocobalamin Injection, USP

## Safety Data Sheet

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

**Skin Corrosion/Irritation:** Not classified

**pH:** 4.5 - 7.0

**Serious Eye Damage/Irritation:** Not classified

**pH:** 4.5 - 7.0

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

**Hydrochloric acid (7647-01-0)**

**IARC group**

3

**Reproductive Toxicity:** Not classified

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** Overexposure may be irritating to the respiratory system.

**Symptoms/Injuries After Skin Contact:** Contact during a long period may cause slight irritation.

**Symptoms/Injuries After Eye Contact:** Direct contact with the eyes is likely irritating.

**Symptoms/Injuries After Ingestion:** Ingestion is likely to be harmful or have adverse effects. May cause gastrointestinal irritation, nausea, vomiting and diarrhea.

**Chronic Symptoms:** None expected under normal conditions of use.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Benzyl alcohol (100-51-6)**

**LC50 Fish 1** 460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])

**EC50 Daphnia 1** 23 mg/l (Exposure time: 48 h - Species: water flea)

**LC 50 Fish 2** 10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

**ErC50 (algae)** 770 mg/l

**Sodium chloride (7647-14-5)**

**LC50 Fish 1** 5560 (5560 - 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])

**EC50 Daphnia 1** 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)

**LC 50 Fish 2** 12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

**EC50 Daphnia 2** 340.7 (340.7 - 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

**Sodium hydroxide (1310-73-2)**

**LC50 Fish 1** 45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

**EC50 Daphnia 1** 40 mg/l

**Hydrochloric acid (7647-01-0)**

**LC50 Fish 1** 3.25 - 3.5 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)

**EC50 Daphnia 1** 4.92 mg/l (Exposure time: 48 h - Species: Daphnia magna)

### 12.2. Persistence and Degradability

No additional information available

### 12.3. Bioaccumulative Potential

**Cyanocobalamin Injection, USP**

**Bioaccumulative Potential** Not expected to bioaccumulate.

**Benzyl alcohol (100-51-6)**

**Log Pow** 1.1

**Sodium chloride (7647-14-5)**

**BCF fish 1** (no bioaccumulation)

### 12.4. Mobility in Soil

No additional information available

### 12.5. Other Adverse Effects

**Other Information** : Avoid release to the environment.

# Cyanocobalamin Injection, USP

## Safety Data Sheet

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

### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1. Waste treatment methods

**Waste Disposal Recommendations:** Dispose of waste material in accordance with all local, regional, national, and international regulations.

**Ecology – Waste Materials:** Avoid release to the environment.

### SECTION 14: TRANSPORT INFORMATION

**14.1. In Accordance with DOT** Not regulated for transport

**14.2. In Accordance with IMDG** Not regulated for transport

**14.3. In Accordance with IATA** Not regulated for transport

### SECTION 15: REGULATORY INFORMATION

#### 15.1 US Federal Regulations

##### Cyanocobalamin (68-19-9)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

##### Benzyl alcohol (100-51-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

##### Sodium chloride (7647-14-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

##### Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

##### SARA Section 311/312 Hazard Classes

Immediate (acute) health hazard

##### Hydrochloric acid (7647-01-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Listed on the United States SARA Section 302

Listed on United States SARA Section 313

##### SARA Section 302 Threshold Planning Quantity (TPQ)

500 (gas only)

##### SARA Section 311/312 Hazard Classes

Immediate (acute) health hazard

##### SARA Section 313 - Emission Reporting

1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

##### Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

#### 15.2 US State Regulations

##### Benzyl alcohol (100-51-6)

U.S. - Massachusetts - Right To Know List

U.S. - Pennsylvania - RTK (Right to Know) List

##### Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List

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

U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

U.S. - Pennsylvania - RTK (Right to Know) List

##### Hydrochloric acid (7647-01-0)

U.S. - Massachusetts - Right To Know List

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

U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

U.S. - Pennsylvania - RTK (Right to Know) List

### SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Revision Date** : 11/12/2015

**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

#### GHS Full Text Phrases:

Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2

## Cyanocobalamin Injection, USP

### Safety Data Sheet

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

Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 4	Flammable liquids Category 4
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H227	Combustible liquid
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H401	Toxic to aquatic life
H402	Harmful to aquatic life

Refer to Luitpold/American Regent prescribing information for further information at:  
<http://www.americanregent.com/AllProducts.aspx>

*The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.*

SDS US (GHS HazCom)





# US - OSHA SAFETY DATA SHEET

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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.

DAPTACEL

Revision Date 22-Jan-2019

### 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.



DAPTACEL

Revision Date 22-Jan-2019

**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**

<b>Physical state</b>	Liquid	<b>Odor</b>	Not available.
<b>Appearance</b>	Cloudy suspension.	<b>Odor threshold</b>	Not available.
<b>Color</b>	White.		

DAPTACEL

Revision Date 22-Jan-2019

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
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.	
 <u>Other Information</u>		
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.

**DAPTACEL**

Revision Date 22-Jan-2019

**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**

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

DAPTACEL

Revision Date 22-Jan-2019

#### 14. TRANSPORT INFORMATION

<u>DOT</u>	Not regulated.
<u>TDG</u>	Not regulated.
<u>MEX</u>	Not regulated.
<u>ICAO (air)</u>	Not regulated.
<u>IATA</u>	Not regulated.
<u>IMDG</u>	Not regulated.
<u>RID</u>	Not regulated.
<u>ADR</u>	Not regulated.
<u>ADN</u>	Not regulated.

#### 15. REGULATORY INFORMATION

##### US Federal Regulations

##### SARA 313

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

##### SARA 311/312 Hazard Categories

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

##### CWA (Clean Water Act)

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

##### CERCLA

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

##### US State Regulations

##### California Proposition 65

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.

DAPTACEL

Revision Date 22-Jan-2019

**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

Revision date: 23-Mar-2017

Version: 3.1

Page 1 of 10

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

#### Product Identifier

**Material Name:** Methylprednisolone Acetate Suspension, USP, Sterile

**Trade Name:** Depo-Medrol  
**Chemical Family:** Mixture

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

**Intended Use:** Pharmaceutical product used as anti-inflammatory

#### Details of the Supplier of the Safety Data Sheet

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

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

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

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

### 2. HAZARDS IDENTIFICATION

#### Classification of the Substance or Mixture

##### GHS - Classification

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

#### Label Elements

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

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

## SAFETY DATA SHEET

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

Page 2 of 10

Version: 3.1

**Other Hazards**

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

**Note:**

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

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

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

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

**Additional Information:**

\* Proprietary

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

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

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

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

**Skin Contact:**

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

**Ingestion:**

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



## SAFETY DATA SHEET

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

Page 3 of 10

Version: 3.1

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

**Most Important Symptoms and Effects, Both Acute and Delayed**

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

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

**5. FIRE FIGHTING MEASURES**

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

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** May include oxides of carbon.

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

**Advice for Fire-Fighters**

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

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

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

**Environmental Precautions**

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

**Methods and Material for Containment and Cleaning Up**

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

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

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

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

**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

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

## SAFETY DATA SHEET

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

Page 4 of 10

Version: 3.1

**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 <sup>3</sup>
Czech Republic OEL - TWA	40 mg/m <sup>3</sup>
Finland OEL - TWA	10 ppm
	45 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Poland OEL - TWA	240 mg/m <sup>3</sup>

**Methylprednisolone Acetate**

Pfizer OEL TWA-8 Hr: 4µg/m<sup>3</sup>, Skin

**Polyethylene glycol**

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

**Sodium phosphate, dibasic**

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

**Sodium phosphate, monobasic**

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

**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.)

## SAFETY DATA SHEET

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

Page 5 of 10

Version: 3.1

## 9. PHYSICAL AND CHEMICAL PROPERTIES

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

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

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

**Methylprednisolone Acetate**

No data available

**Methylprednisolone**

Predicted 7.4 Log D 1.99

**Water**

No data available

**Polyethylene glycol**

No data available

**Polysorbate 80**

No data available

**Sodium phosphate, dibasic**

No data available

**Sodium phosphate, monobasic**

No data available

**Benzyl Alcohol**

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

**Flammability:**

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

**Flammability (Solids):** No data available

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

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

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

**Polymerization:**

Will not occur

## 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions**

**Oxidizing Properties:** No data available

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

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

## SAFETY DATA SHEET

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

Page 6 of 10

Version: 3.1

**10. STABILITY AND REACTIVITY**

Hazardous Decomposition      No data available  
Products:

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

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

**Short Term:**

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

**Long Term:**

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

**Known Clinical Effects:**

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

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

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

**Methylprednisolone**

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

**Polysorbate 80**

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

**Benzyl Alcohol**

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

**Acute Toxicity Comments:**

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

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

Eye Irritation Rabbit No effect  
Skin Irritation Rabbit No effect

## SAFETY DATA SHEET

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

Page 7 of 10

Version: 3.1

**11. TOXICOLOGICAL INFORMATION****Methylprednisolone**

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

**Polyethylene glycol**

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

**Benzyl Alcohol**

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

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

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

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

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

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

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

**Methylprednisolone**

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

**Carcinogen Status:**

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

## SAFETY DATA SHEET

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

Page 8 of 10

Version: 3.1

## 12. ECOLOGICAL INFORMATION

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

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

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

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

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

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

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

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

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

**Bio-accumulative Potential:** No data available

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

Predicted 7.4 Log D 1.99

**Mobility in Soil:** No data available

## 13. DISPOSAL CONSIDERATIONS

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

## 14. TRANSPORT INFORMATION

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

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

## SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Suspension, USP,  
Sterile

Page 9 of 10

Revision date: 23-Mar-2017

Version: 3.1

## 15. REGULATORY INFORMATION

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

#### Benzyl Alcohol

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

#### Methylprednisolone Acetate

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

#### Polyethylene glycol

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

#### Polysorbate 80

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

#### Sodium phosphate, dibasic

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

#### Sodium phosphate, monobasic

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

## SAFETY DATA SHEET

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

Page 10 of 10

Version: 3.1

## 15. REGULATORY INFORMATION

## Water

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

## 16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

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

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

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

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

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

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

End of Safety Data Sheet



# Donnatal® Elixir Grape Flavored

## SAFETY DATA SHEET

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

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

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

#### 1.1. Product identifier

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

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

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

#### 1.3. Details of the supplier of the safety data sheet

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

#### 1.4. Emergency telephone number

Emergency number : 1-800-858-4006

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification (GHS-US)

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

#### 2.2. Label elements

##### GHS-US labeling

Hazard pictograms (GHS-US) :



Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

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

Precautionary statements (GHS-US) :

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

# Donnatal® Elixir Grape Flavored

## SAFETY DATA SHEET

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

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

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

### 2.3. Other hazards

No additional information available

### 2.4. Unknown acute toxicity (GHS-US)

No data available

## SECTION 3: Composition/information on ingredients

### 3.1. Substance

Not applicable

### 3.2. Mixture

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

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

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

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

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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

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

### 5.2. Special hazards arising from the substance or mixture

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

# Donnatal® Elixir Grape Flavored

## SAFETY DATA SHEET

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

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

### 5.3. Advice for firefighters

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

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

#### 6.1.2. For emergency responders

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

### 6.2. Environmental precautions

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

### 6.3. Methods and material for containment and cleaning up

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

### 6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

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

### 7.2. Conditions for safe storage, including any incompatibilities

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

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

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

### 8.2. Exposure controls

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

# Donnatal® Elixir Grape Flavored

## SAFETY DATA SHEET

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

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

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

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

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state : Liquid

Color : Clear; purple

Odor : Grape

Odor threshold : No data available

pH : 4,5 - 5,5

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

Melting point : No data available

Freezing point : No data available

Boiling point : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Flammability (solid, gas) : No data available

Vapor pressure : No data available

Relative vapor density at 20 °C : No data available

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

Solubility : Water: infinitely soluble

Log Pow : No data available

Log Kow : No data available

Viscosity, kinematic : No data available

Viscosity, dynamic : 15 cP @ 25°C

Explosive properties : No data available

Oxidizing properties : No data available

Explosive limits : No data available

#### 9.2. Other information

No additional information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Not expected to present a significant hazard under anticipated conditions of normal use.

#### 10.2. Chemical stability

Anticipated to be stable under anticipated conditions of normal use.

#### 10.3. Possibility of hazardous reactions

Not expected to present a significant hazard under anticipated conditions of normal use.

#### 10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

#### 10.5. Incompatible materials

Strong acids, strong bases, strong oxidizers, alkali metals, sodium hydroxide.

#### 10.6. Hazardous decomposition products

Fume, carbon monoxide, carbon dioxide, nitrogen oxides and may form small quantities of acrolein.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity : Not classified

#### ethanol, ethyl alcohol (64-17-5)

LD50 oral mouse	3450 mg/kg
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# Donnatal® Elixir Grape Flavored

## SAFETY DATA SHEET

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

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

ethanol, ethyl alcohol (64-17-5)	
LD50 dermal rabbit	> 15800 mg/kg
LC50 inhalation mouse (ppm)	21000 ppm/4h

Phenobarbital	
LD50 oral mouse	112 mg/kg
LC50 inhalation rat (mg/l)	> 4100 µg/m³

Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Suspected of causing cancer.

Phenobarbital	
IARC group	2B - Possibly Carcinogenic to Humans  Phenobarbital is carcinogenic in mice and rats after lifetime administration. In mice it produced benign and malignant liver cell tumors. In rats, benign liver cell tumors were observed. Phenobarbital was negative in a 26 week bioassay in p53 heterozygous mice. Genotoxicity studies for gene mutations and chromosome aberrations have given mixed results, however tests for DNA damage or repair have been negative.

Reproductive toxicity	: May damage fertility or the unborn child.
Specific target organ toxicity (single exposure)	: May cause drowsiness or dizziness. May cause respiratory irritation.
Specific target organ toxicity (repeated exposure)	: Not classified (Lack of data)
Aspiration hazard	: May be fatal if swallowed and enters airways.
Potential Adverse human health effects and symptoms	: See above. No additional health hazards are known.
Symptoms/injuries after inhalation	: May cause an allergic skin reaction. May cause respiratory irritation. May cause drowsiness or dizziness.
Symptoms/injuries after eye contact	: Causes serious eye irritation.

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: Not determined.
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### 12.2. Persistence and degradability

DONNATAL ELIXIR - GRAPE	
Persistence and degradability	Not established.

### 12.3. Bioaccumulative potential

DONNATAL ELIXIR - GRAPE	
Bioaccumulative potential	Not established.

### 12.4. Mobility in soil

DONNATAL ELIXIR - GRAPE	
Ecology - soil	Not determined.

### 12.5. Other adverse effects

Effect on ozone layer	: No additional information available
Effect on global warming	: Not determined.
Other information	: Avoid release to the environment.

# Donnatal® Elixir Grape Flavored

## SAFETY DATA SHEET

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

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

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.  
Ecology - waste materials : Avoid release to the environment.

### SECTION 14: Transport information

In accordance with DOT

Not determined

#### Additional information

Other information : No supplementary information available.

#### Transport by sea

No additional information available

#### Air transport

No additional information available

### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

No additional information available

#### 15.2. International regulations

##### CANADA

Not determined

##### EU-Regulations

No additional information available

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not determined

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

Not determined

#### 15.2.2. National regulations

No additional information available

#### 15.3. US State regulations

Not determined

### SECTION 16: Other information

References : Available upon request

Other information : None.

Full text of H-phrases: see sections 2 & 3:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Asp. Tox. 1	Aspiration hazard Category 1
Carc. 2	Carcinogenicity Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Repr. 1A	Reproductive toxicity Category 1A
Skin Sens. 1	Skin sensitization Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H301	Toxic if swallowed
H304	May be fatal if swallowed and enters airways
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H335	May cause respiratory irritation

# Donnatal® Elixir Grape Flavored

## SAFETY DATA SHEET

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

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

H336	May cause drowsiness or dizziness
H351	Suspected of causing cancer
H360	May damage fertility or the unborn child

SDS US (GHS HazCom 2012)

*This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material in an industrial setting. It is not meant to be an all-inclusive document on worldwide hazard communication regulations. This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate mechanisms to prevent employee exposures, property damage or release to the environment. Refer to Product Monograph for pharmaceutical use information.*







# SAFETY DATA SHEET

## 1. Identification

**Product identifier** ENGERIX-B

**Other means of identification**

**Synonyms**

ENERGIX 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

**Telephone:**

CHEMTREC EMERGENCY NUMBERS

+(1) 703 527 3887 (International)

24/7; multi-language response

**Contract Number:**

CCN9484

**Telephone:**

VERISK 3E GLOBAL INCIDENT RESPONSE

+(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

<b>Inhalation</b>	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.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	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.
<b>Most important symptoms/effects, acute and delayed</b>	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 (CO<sub>2</sub>).

**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. Avoid discharge into drains, water courses or onto the ground.

**Environmental precautions****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/m<sup>3</sup>

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/m<sup>3</sup>

TWA

0.01 mg/m<sup>3</sup>

**US. ACGIH Threshold Limit Values**

Components	Type	Value	Form
ALUMINIUM HYDROXIDE (CAS 21645-51-2)	TWA	1 mg/m <sup>3</sup>	Respirable fraction.
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)	STEL	0.03 mg/m <sup>3</sup>	
	TWA	0.01 mg/m <sup>3</sup>	

**US. NIOSH: Pocket Guide to Chemical Hazards**

Components	Type	Value
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)	STEL	0.03 mg/m <sup>3</sup>
	TWA	0.01 mg/m <sup>3</sup>

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

**Exposure guidelines****US - California OELs: Skin designation**

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

**US - Tennessee OELs: Skin designation**

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

**US ACGIH Threshold Limit Values: Skin designation**

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

**US NIOSH Pocket Guide to Chemical Hazards: Skin designation**

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

**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.

<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.

**Upper/lower flammability or explosive limits**

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.

<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.

**Solubility(ies)**

<b>Solubility (water)</b>	Not available.
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<b>Partition coefficient (n-octanol/water)</b>	Not available.
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<b>Auto-ignition temperature</b>	Not available.
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<b>Decomposition temperature</b>	Not available.
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<b>Viscosity</b>	Not available.
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**Other information**

<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions. DO NOT FREEZE - dispose of properly if frozen.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	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**

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	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.
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	None known.

**Information on toxicological effects**

<b>Acute toxicity</b>	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
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<b>Components</b>	<b>Species</b>	<b>Test Results</b>
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)		
<u><b>Acute</b></u>		
<b>Oral</b>		
LD50	Rat	17 g/kg

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

<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.
<b>Serious eye damage/eye irritation</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
<b>Respiratory or skin sensitization</b>	
<b>Respiratory sensitization</b>	No studies have been conducted.
<b>Skin sensitization</b>	None known. This product is not expected to cause skin sensitization.
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>Carcinogenicity</b>	Carcinogenic effects are not expected as a result of occupational exposure. Not classifiable as to carcinogenicity to humans.
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>	
Not listed.	
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	
Not regulated.	
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>	
Not listed.	
<b>Reproductive toxicity</b>	Contains no ingredient listed as toxic to reproduction
<b>Specific target organ toxicity - single exposure</b>	Not assigned.
<b>Specific target organ toxicity - repeated exposure</b>	Not assigned.
<b>Aspiration hazard</b>	Not established.
<b>Chronic effects</b>	Prolonged inhalation may be harmful.
<b>Further information</b>	Occupational exposure to the substance or mixture may cause adverse effects.

## 12. Ecological information

<b>Ecotoxicity</b>	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.
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Components		Species	Test Results
ALUMINIUM HYDROXIDE (CAS 21645-51-2)			
<b>Aquatic</b>			
<i>Acute</i>			
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)			
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	252 mg/l

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

<b>Persistence and degradability</b>	Not available.
<b>Bioaccumulative potential</b>	Not available.
<b>Mobility in soil</b>	Not available.
<b>Mobility in general</b>	Not available.
<b>Other adverse effects</b>	Not available.

## 13. Disposal considerations

<b>Disposal instructions</b>	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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

<b>Waste from residues / unused products</b>	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.
<b>Contaminated packaging</b>	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

<b>Issue date</b>	05-29-2018
<b>Revision date</b>	05-29-2018
<b>Version #</b>	18
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 1 Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	Health: 1 Flammability: 0 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.
<b>Revision information</b>	This document has undergone significant changes and should be reviewed in its entirety.





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

## Section 5: FIRE FIGHTING MEASURES

### Special Fire Fighting Procedures

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

### Unusual Fire and Explosion Hazards

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

## Section 6: ACCIDENTAL RELEASE MEASURES

### Spill and Leak Response

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

### Waste Disposal Method

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

## Section 7: HANDLING AND STORAGE

### Storage Precautions

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

### Handling Precautions

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

## Section 8: EXPOSURE CONTROLS – PERSONAL PROTECTION

### Engineering Controls

Use with adequate ventilation.

### Respiratory Protection

For clinical setting: minimize inhalation of vapors by patient, especially when applying to head and neck. For large spills ( $\geq 1000$  ppm twa and  $\leq 3800$  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  $\geq 1000$  ppm TWA and  $\leq 3800$  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

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

## Section 10: STABILITY AND REACTIVITY

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

## Section 11: TOXICOLOGICAL INFORMATION

<b>Routes of Exposure:</b>	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.
<b>Effects of overexposure:</b>	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.
Acute	
Sub Chronic	Increased liver weights were observed in rats and mice after exposure to 2500, 5000, 10,000 and 19,000 ppm for 6 hours/day, 5 days/week for 13 weeks. No other effects were observed in the study.
Carcinogenicity	Carcinomas of the uterus were observed in female mice exposed to 15,000 ppm during the course of a 2-year inhalation study.

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



## SIGMA-ALDRICH

sigma-aldrich.com

## SAFETY DATA SHEET

Version 4.12  
 Revision Date 09/23/2016  
 Print Date 02/17/2018

## 1. PRODUCT AND COMPANY IDENTIFICATION

## 1.1 Product identifiers

Product name : Formalin solution, neutral buffered, 10%

Product Number : HT501128

Brand : Sigma

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

Identified uses : Laboratory chemicals, Synthesis of substances

## 1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich  
 3050 Spruce Street  
 SAINT LOUIS MO 63103  
 USA

Telephone : +1 800-325-5832

Fax : +1 800-325-5052

## 1.4 Emergency telephone number

Emergency Phone # : +1-703-527-3887 (CHEMTREC)

## 2. HAZARDS IDENTIFICATION

## 2.1 Classification of the substance or mixture

## GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Flammable liquids (Category 4), H227

Acute toxicity, Oral (Category 4), H302

Skin irritation (Category 2), H315

Serious eye damage (Category 1), H318

Skin sensitisation (Category 1), H317

Germ cell mutagenicity (Category 2), H341

Carcinogenicity (Category 1A), H350

Specific target organ toxicity - single exposure (Category 1), H370

For the full text of the H-Statements mentioned in this Section, see Section 16.

## 2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word

Danger

Hazard statement(s)

H227

Combustible liquid.

H302

Harmful if swallowed.

H315

Causes skin irritation.

H317

May cause an allergic skin reaction.

H318

Causes serious eye damage.

H341

Suspected of causing genetic defects.

H350

May cause cancer.

H370

Causes damage to organs.

## Precautionary statement(s)

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P210	Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P260	Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264	Wash skin thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P301 + P312 + P330	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
P307 + P311	IF exposed: Call a POISON CENTER or doctor/ physician.
P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
P362	Take off contaminated clothing and wash before reuse.
P370 + P378	In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.
P403 + P235	Store in a well-ventilated place. Keep cool.
P405	Store locked up.
P501	Dispose of contents/ container to an approved waste disposal plant.

**2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none****3. COMPOSITION/INFORMATION ON INGREDIENTS****3.2 Mixtures****Hazardous components**

Hazardous components		Classification	Concentration
Formaldehyde			
CAS-No.	50-00-0	Flam. Liq. 4; Acute Tox. 3; Skin Corr. 1B; Eye Dam. 1; Skin Sens. 1; Muta. 2; Carc. 1A; Aquatic Acute 3; H227, H301 + H311 + H331, H314, H317, H341, H350, H402	>= 1 - < 5 %
EC-No.	200-001-8		
Index-No.	605-001-00-5		
Registration number	01-2119488953-20-0169		
Methanol			
CAS-No.	67-56-1	Flam. Liq. 2; Acute Tox. 3; STOT SE 1; H225, H301 + H311 + H331, H370	>= 1 - < 5 %
EC-No.	200-659-6		
Index-No.	603-001-00-X		
Registration number	01-2119433307-44-XXXX		

For the full text of the H-Statements mentioned in this Section, see Section 16.

**4. FIRST AID MEASURES****4.1 Description of first aid measures****General advice**

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

**If inhaled**

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

**In case of skin contact**

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

**In case of eye contact**

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

**If swallowed**

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

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

No data available

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**5. FIREFIGHTING MEASURES****5.1 Extinguishing media****Suitable extinguishing media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**5.2 Special hazards arising from the substance or mixture**

No data available

**5.3 Advice for firefighters**

Wear self-contained breathing apparatus for firefighting if necessary.

**5.4 Further information**

Use water spray to cool unopened containers.

---

**6. ACCIDENTAL RELEASE MEASURES****6.1 Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas.  
For personal protection see section 8.

**6.2 Environmental precautions**

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

**6.3 Methods and materials for containment and cleaning up**

Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13). Keep in suitable, closed containers for disposal.

**6.4 Reference to other sections**

For disposal see section 13.

---

**7. HANDLING AND STORAGE****7.1 Precautions for safe handling**

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.  
Keep away from sources of ignition - No smoking. Take measures to prevent the build up of electrostatic charge.  
For precautions see section 2.2.

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

Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

**7.3 Specific end use(s)**

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

---

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1 Control parameters**

**Components with workplace control parameters**

Component	CAS-No.	Value	Control parameters	Basis
Formaldehyde	50-00-0	C	0.300000 ppm	USA. ACGIH Threshold Limit Values (TLV)
	Remarks	Upper Respiratory Tract irritation Eye irritation Suspected human carcinogen Sensitizer		
		TWA	0.016000 ppm	USA. NIOSH Recommended Exposure Limits
		Potential Occupational Carcinogen See Appendix A		
		C	0.100000 ppm	USA. NIOSH Recommended Exposure Limits
		Potential Occupational Carcinogen See Appendix A 15 minute ceiling value		
		Substance listed; for more information see OSHA document 1910.1048		
		Substance listed; for more information see OSHA document 1910.1048		
		PEL	0.750000 ppm	OSHA Specifically Regulated Chemicals/Carcinogens
		1910.1048 This standard applies to all occupational exposures to formaldehyde, i.e. from formaldehyde gas, its solutions, and materials that release formaldehyde OSHA specifically regulated carcinogen		
		STEL	2.000000 ppm	OSHA Specifically Regulated Chemicals/Carcinogens
		1910.1048 This standard applies to all occupational exposures to formaldehyde, i.e. from formaldehyde gas, its solutions, and materials that release formaldehyde OSHA specifically regulated carcinogen		
		TWA	0.016000 ppm	USA. NIOSH Recommended Exposure Limits
		Potential Occupational Carcinogen Formalin is an aqueous solution that is 37% formaldehyde by weight; inhibited solutions usually contain 6-12% methyl alcohol. Also see specific listings for Formaldehyde and Methyl alcohol. See Appendix A		
		C	0.100000 ppm	USA. NIOSH Recommended Exposure Limits
		Potential Occupational Carcinogen Formalin is an aqueous solution that is 37% formaldehyde by weight; inhibited solutions usually contain 6-12% methyl alcohol. Also see specific listings for Formaldehyde and Methyl alcohol. See Appendix A 15 minute ceiling value		
		C	0.3 ppm	USA. ACGIH Threshold Limit Values (TLV)
		Dermal Sensitization Respiratory sensitization Upper Respiratory Tract irritation Eye irritation 2015 Adoption Suspected human carcinogen		



		TWA	0.016 ppm	USA. NIOSH Recommended Exposure Limits
		Potential Occupational Carcinogen Formalin is an aqueous solution that is 37% formaldehyde by weight; inhibited solutions usually contain 6-12% methyl alcohol. Also see specific listings for Formaldehyde and Methyl alcohol. See Appendix A		
		C	0.1 ppm	USA. NIOSH Recommended Exposure Limits
		Potential Occupational Carcinogen Formalin is an aqueous solution that is 37% formaldehyde by weight; inhibited solutions usually contain 6-12% methyl alcohol. Also see specific listings for Formaldehyde and Methyl alcohol. See Appendix A 15 minute ceiling value		
		PEL	0.75 ppm	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
		see Section 5217		
		STEL	2 ppm	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
		see Section 5217		
Methanol	67-56-1	TWA	200.000000 ppm	USA. ACGIH Threshold Limit Values (TLV)
		Headache Nausea Dizziness Eye damage Substances for which there is a Biological Exposure Index or Indices (see BEI® section) Danger of cutaneous absorption		
		STEL	250.000000 ppm	USA. ACGIH Threshold Limit Values (TLV)
		Headache Nausea Dizziness Eye damage Substances for which there is a Biological Exposure Index or Indices (see BEI® section) Danger of cutaneous absorption		
		TWA	200.000000 ppm 260.000000 mg/m3	USA. NIOSH Recommended Exposure Limits
		Potential for dermal absorption		
		ST	250.000000 ppm 325.000000 mg/m3	USA. NIOSH Recommended Exposure Limits
		Potential for dermal absorption		
		TWA	200.000000 ppm 260.000000 mg/m3	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		The value in mg/m3 is approximate.		

		TWA	200 ppm	USA. ACGIH Threshold Limit Values (TLV)
		Headache Nausea Dizziness Eye damage Substances for which there is a Biological Exposure Index or Indices (see BEI® section) Danger of cutaneous absorption		
		STEL	250 ppm	USA. ACGIH Threshold Limit Values (TLV)
		Headache Nausea Dizziness Eye damage Substances for which there is a Biological Exposure Index or Indices (see BEI® section) Danger of cutaneous absorption		
		TWA	200 ppm 260 mg/m3	USA. NIOSH Recommended Exposure Limits
		Potential for dermal absorption		
		ST	250 ppm 325 mg/m3	USA. NIOSH Recommended Exposure Limits
		Potential for dermal absorption		
		TWA	200 ppm 260 mg/m3	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		The value in mg/m3 is approximate.		
		STEL	250 ppm 325 mg/m3	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
		Skin notation		
		TWA	200 ppm 260 mg/m3	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
		Skin notation		
		C	1,000 ppm	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
		Skin		
		PEL	200 ppm 260 mg/m3	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
		Skin		
		STEL	250 ppm 325 mg/m3	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
		Skin		

#### Biological occupational exposure limits

Component	CAS-No.	Parameters	Value	Biological specimen	Basis
Methanol	67-56-1	Methanol	15.0000 mg/l	Urine	ACGIH - Biological Exposure Indices (BEI)
	Remarks	End of shift (As soon as possible after exposure ceases)			
		Methanol	15 mg/l	Urine	ACGIH - Biological Exposure Indices (BEI)
		End of shift (As soon as possible after exposure ceases)			

## 8.2 Exposure controls

### Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

### Personal protective equipment

#### Eye/face protection

Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

#### Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested: Dermatrill® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested: Dermatrill® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

#### Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

#### Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

#### Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

---

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

- |  |   |
|--|---|
| a) Appearance                              | Form: liquid                            |
| b) Odour                                   | No data available                       |
| c) Odour Threshold                         | No data available                       |
| d) pH                                      | No data available                       |
| e) Melting point/freezing point            | No data available                       |
| f) Initial boiling point and boiling range | 100 °C (212 °F) at 1,013 hPa (760 mmHg) |
| g) Flash point                             | 85 °C (185 °F)                          |
| h) Evaporation rate                        | No data available                       |

- |   |   |
|---|---|
| i) Flammability (solid, gas)                    | No data available   |
| j) Upper/lower flammability or explosive limits | Upper explosion limit: 70 %(V)<br>Lower explosion limit: 7 %(V) |
| k) Vapour pressure                              | 53 hPa (40 mmHg) at 39 °C (102 °F)                              |
| l) Vapour density                               | No data available   |
| m) Relative density                             | 1.080 g/cm <sup>3</sup>   |
| n) Water solubility                             | completely miscible   |
| o) Partition coefficient: n-octanol/water       | No data available   |
| p) Auto-ignition temperature                    | No data available   |
| q) Decomposition temperature                    | No data available   |
| r) Viscosity                                    | No data available   |
| s) Explosive properties                         | No data available   |
| t) Oxidizing properties                         | No data available   |

## 9.2 Other safety information

No data available

---

## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

No data available

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No data available

### 10.4 Conditions to avoid

Heat, flames and sparks.

### 10.5 Incompatible materials

Strong bases, Acids, Oxidizing agents, Alkali metals, Strong oxidizing agents, Amines, Strong acids, Acid chlorides, Acid anhydrides, Reducing agents, Peroxides, Isocyanates, Phenol, Aniline

### 10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides

Other decomposition products - No data available

In the event of fire: see section 5

---

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute toxicity

No data available

Inhalation: No data available

Dermal: No data available

No data available

#### Skin corrosion/irritation

No data available

#### Serious eye damage/eye irritation

No data available

**Respiratory or skin sensitisation**

No data available

**Germ cell mutagenicity**

No data available

**Carcinogenicity**

IARC: 1 - Group 1: Carcinogenic to humans (Formaldehyde)

NTP: Known to be human carcinogen (Formaldehyde)

OSHA: OSHA specifically regulated carcinogen (Formaldehyde)

**Reproductive toxicity**

No data available

No data available

**Specific target organ toxicity - single exposure**

No data available

**Specific target organ toxicity - repeated exposure**

No data available

**Aspiration hazard**

No data available

**Additional Information**

RTECS: Not available

Methyl alcohol may be fatal or cause blindness if swallowed., Cannot be made non-poisonous., Effects due to ingestion may include:, Nausea, Dizziness, Gastrointestinal disturbance, Weakness, Confusion., Drowsiness, Unconsciousness, May cause convulsions.

Liver - Irregularities - Based on Human Evidence

Stomach - Irregularities - Based on Human Evidence

Liver - Irregularities - Based on Human Evidence (Formaldehyde)

Stomach - Irregularities - Based on Human Evidence (Methanol)

---

**12. ECOLOGICAL INFORMATION****12.1 Toxicity**

No data available

**12.2 Persistence and degradability**

No data available

**12.3 Bioaccumulative potential**

No data available

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

**12.6 Other adverse effects**

No data available

---

**13. DISPOSAL CONSIDERATIONS****13.1 Waste treatment methods****Product**

This combustible material may be burned in a chemical incinerator equipped with an afterburner and scrubber. Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

**Contaminated packaging**

Dispose of as unused product.

---

**14. TRANSPORT INFORMATION****DOT (US)**

NA-Number: 1993      Class: NONE      Packing group: III  
 Proper shipping name: Combustible liquid, n.o.s. (Formaldehyde, Methanol)  
 Reportable Quantity (RQ): 2500 lbs

Poison Inhalation Hazard: No

**IMDG**

Not dangerous goods

**IATA**

Not dangerous goods

---

**15. REGULATORY INFORMATION****SARA 302 Components**

The following components are subject to reporting levels established by SARA Title III, Section 302:

	CAS-No.	Revision Date
Formaldehyde	50-00-0	2007-07-01

**SARA 313 Components**

The following components are subject to reporting levels established by SARA Title III, Section 313:

	CAS-No.	Revision Date
Methanol	67-56-1	2007-07-01
Formaldehyde	50-00-0	2007-07-01

**SARA 311/312 Hazards**

Fire Hazard, Acute Health Hazard, Chronic Health Hazard

**Massachusetts Right To Know Components**

	CAS-No.	Revision Date
Formaldehyde	50-00-0	2007-07-01
Methanol	67-56-1	2007-07-01

**Pennsylvania Right To Know Components**

	CAS-No.	Revision Date
Water	7732-18-5	
Formaldehyde	50-00-0	2007-07-01
Methanol	67-56-1	2007-07-01
Disodium hydrogenorthophosphate	7558-79-4	2007-03-01

**New Jersey Right To Know Components**

	CAS-No.	Revision Date
Water	7732-18-5	
Formaldehyde	50-00-0	2007-07-01
Methanol	67-56-1	2007-07-01

**California Prop. 65 Components**

	CAS-No.	Revision Date
WARNING! This product contains a chemical known to the State of California to cause cancer.	50-00-0	2007-09-28
Formaldehyde		

	CAS-No.	Revision Date
WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.	67-56-1	2012-03-16
Methanol		

## 16. OTHER INFORMATION

### Full text of H-Statements referred to under sections 2 and 3.

Acute Tox.	Acute toxicity
Aquatic Acute	Acute aquatic toxicity
Carc.	Carcinogenicity
Eye Dam.	Serious eye damage
Flam. Liq.	Flammable liquids
H225	Highly flammable liquid and vapour.
H227	Combustible liquid.
H301 + H311 + H331	Toxic if swallowed, in contact with skin or if inhaled
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H370	Causes damage to organs.
H402	Harmful to aquatic life.
Muta.	Germ cell mutagenicity
Skin Corr.	Skin corrosion
Skin Sens.	Skin sensitisation
STOT SE	Specific target organ toxicity - single exposure

### HMIS Rating

Health hazard:	3
Chronic Health Hazard:	*
Flammability:	2
Physical Hazard	0

### NFPA Rating

Health hazard:	3
Fire Hazard:	2
Reactivity Hazard:	0

### Further information

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### Preparation Information

Sigma-Aldrich Corporation  
Product Safety – Americas Region  
1-800-521-8956

Version: 4.12

Revision Date: 09/23/2016

Print Date: 02/17/2018





# Gardasil®



## SAFETY DATA SHEET

Page 1 of 6 - Date of Issue: 15 November 2016

**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

<b>Product Name</b>	Gardasil®
<b>Other Names</b>	Human Papillomavirus Quadrivalent (types 6, 11, 16 and 18), Vaccine, Recombinant: HPV Vaccine
<b>Manufacturer's Product Code</b>	S30383, S30384, S30385, S30386
<b>Use</b>	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.
<b>Supplier Name</b>	Seqirus Pty Ltd (ABN 26 160 735 035)
<b>Address</b>	63 Poplar Road, Parkville, Victoria 3052, Australia
<b>Telephone</b>	+61 3 9389 2000
<b>Emergency Telephone</b>	+61 3 9389 1984 (24hr)

### 2. HAZARDS IDENTIFICATION

**Not classified as a hazardous chemical according to Australian WHS Regulations**

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

## SAFETY DATA SHEET

Gardasil®

Page 2 of 6  
Date of Issue: 15 November 2016

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

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

## 4. FIRST AID MEASURES

<b>Eye</b>	In case of contact, flush eyes with plenty of water. Get medical attention if symptoms occur.
<b>Swallowed</b>	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.
<b>Skin</b>	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.
<b>Inhaled</b>	If inhaled remove to fresh air. If breathing is difficult, give oxygen. If not breathing give artificial respiration. Get medical attention if symptoms occur.
<b>First Aid Facilities</b>	Ensure water is available at point of use.
<b>Advice to Doctor</b>	Treat symptomatically.

## 5. FIRE FIGHTING MEASURES

<b>Fire/Explosion Hazard</b>	None known.
<b>Fire Extinguishing Media</b>	<ul style="list-style-type: none"> <li>- Dry chemical powder</li> <li>- Water spray or fog</li> <li>- Foam</li> <li>- Carbon Dioxide</li> </ul>
<b>Hazchem Code</b>	None allocated

## 6. ACCIDENTAL RELEASE MEASURES

<b>Minor Spills</b>	<ul style="list-style-type: none"> <li>- Contain spilled material.</li> <li>- Use absorbent (or soil in the absence of other suitable material)</li> <li>- Scoop up material and place in a sealed, liquid-proof container for disposal.</li> </ul>
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## SAFETY DATA SHEET

Gardasil®

Page 3 of 6  
Date of Issue: 15 November 2016

- |                     |  |
|---------------------|--|
| <b>Major Spills</b> | <ul style="list-style-type: none"> <li>- Contain material ensuring runoff does not reach a waterway.</li> <li>- Place spilled material in an appropriate container for disposal.</li> <li>- Minimise contact of spilled material with solid to prevent runoff to surface waterways.</li> </ul> |
|---------------------|--|

## 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 by 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

- |                             |  |
|-----------------------------|--|
| <b>Exposure Standards</b>   | No exposure limits set by SWA or ACGIH   |
| <b>Engineering Controls</b> | Adequate ventilation should be provided if there is a risk of aerosol formation.   |
| <b>Personal Protection</b>  | 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

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

## SAFETY DATA SHEET

Gardasil®

Page 4 of 6  
Date of Issue: 15 November 2016

## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	Not available
<b>Stability</b>	Not available
<b>Decomposition Products</b>	None known

## 11. TOXICOLOGICAL INFORMATION

<b>Toxicity Data</b>	HPV L1 VLPs- in mouse- no adverse effects except local irritation
<i>Effects of Acute Exposure</i>	
<b>Eye</b>	Formulation may be irritating
<b>Swallowed</b>	Not available
<b>Skin</b>	Formulation may be irritating
<b>Inhaled</b>	Not available
<b>Chronic Health Effects</b>	<p>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® is contraindicated in individuals hypersensitive to any components of the vaccine. Gardasil® is not recommended for pregnant women.</p> <p>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.</p>

## 12. ECOLOGICAL INFORMATION

- No data available.

## SAFETY DATA SHEET

Gardasil®

Page 5 of 6  
Date of Issue: 15 November 2016

## 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

**SAFETY DATA SHEET****Gardasil®**Page 6 of 6  
Date of Issue: 15 November 2016

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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.

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## SAFETY DATA SHEET

Doc. ID: 395185 Rev. AE  
Revised (year/month/day) 2015/04/15

### Section 1 Identification of the Substance/mixture and of the Company/undertaking

#### 1.1 Product Identifier

**Product Name** Hemocult Developer  
**Part Number** 1771, 3060, 395020, 395183, 395184, 395186, 395187, 395245, 395293, 9490  
**Series Name** Hemocult

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

**Product Use** For In Vitro Diagnostic Use. See product literature for details.

#### 1.3 Details of the supplier of the safety data sheet

##### Manufacturer

Beckman Coulter, Inc.  
250 S. Kraemer Blvd  
Brea, CA 92821, U.S.A.  
Tel: 800-854-3633

##### EC REP Address

Beckman Coulter Eurocenter S.A.  
22, rue Juste-Oliver, Case Postale 1044,  
CH-1260 Nyon 1, Switzerland.  
Telephone +41 (0)22 365 36 11  
Monday through Friday, 9:00 am to  
7:00pm)

**e-mail address** SDSNT@beckman.com

#### 1.4 Emergency telephone number

**Telephone number (24H)** Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

##### Distributor and Emergency Phone No.

Refer to attached list, Document ID: [A86357](#), for local distributor and emergency phone numbers.

### Section 2 Hazards Identification

#### 2.1 Classification of substance or mixture

**Product Description** Mixture  
Colorless; Clear; Liquid; Alcohol odor

##### Classification according to EC 1272/2008 (CLP/GHS)

Flammable Liquids, Category 2  
Skin Irritation Category 2  
Eye Damage Category 1

##### Classification according to EC Directives 1999/45/EC and 67/548/EEC

F;R11

**SAFETY DATA SHEET**

Doc. ID: 395185 AE

Revised (year/month/day) 2015/04/15

**Section 2 Hazards Identification (Continued)****Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS**

Flammable Liquids, Category 2

Acute Toxicity Oral, Category 5

Skin Irritation Category 2

Eye Damage Category 1

**2.2 Label Elements****According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS****Hazardous Ingredients**

Ethyl Alcohol

Isopropyl Alcohol

Hydrogen Peroxide

**Pictogram****Signal Word**

DANGER

**Hazard Statements**

H225 Highly flammable liquid and vapour.

H303 May be harmful if swallowed

H315 Causes skin irritation.

H318 Causes serious eye damage.

**Precautionary Statements**

P210 Keep away from heat, hot surfaces, and sparks. No smoking.

P233 Keep container tightly closed.

P240 Ground container and receiving equipment.

P241 Use explosion-proof electrical equipment.

P242 Use non-sparking tools.

P243 Take action to prevent static discharge.

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

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

P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P370+P378 In case of fire: Use water spray for extinction.

P403+P235 Store in a well-ventilated place. Keep cool.

P501 Dispose of contents/container in accordance with local/national regulations  
 Product label will display most significant precautionary statements. 82.2% of product contains ingredients of unknown oral toxicity.



**SAFETY DATA SHEET**
 Doc. ID: 395185 AE  
 Revised (year/month/day) 2015/04/15
**Section 2 Hazards Identification (Continued)****2.3 Other hazards**
 Results of PBT and vPvB assessment  
 PBT: Not applicable.  
 vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

**Section 3 Composition and Information on Ingredients****3.2 Mixtures**

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
Ethyl Alcohol CAS # 64-17-5 EINECS # 200-578-6 Index # 603-002-00-5	75-85	F;R11	Flam. Liq. 2 H225	Flam. Liq. 2 H225	
Hydrogen Peroxide CAS # 7722-84-1 EINECS # 231-765-0 Index # 008-003-00-9	3-6	O;R5-8 C;R35-20/22	Acute Tox. Inhal. 4 Acute Tox. Oral 4 Eye Dam. 1 Ox. Liq. 1 STOT SE 3 Skin Corr. 1A H271; H302; H314; H318; H332; H335	Acute Tox. Inhal. 4 Acute Tox. Oral 4 Eye Dam. 1 Ox. Liq. 1 STOT SE 3 Skin Corr. 1A H271; H302; H314; H318; H332; H335	
Isopropyl Alcohol CAS # 67-63-0 EINECS # 200-661-7 Index # 603-117-00-0	3-6	F;R11 Xi;R36-67	Eye Irrit. 2 Flam. Liq. 2 STOT SE 3 H225; H319; H336	Eye Irrit. 2 Flam. Liq. 2 STOT SE 3 H225; H319; H336	

See section 8 for available Occupational exposure limits

See Section 15 for additional regulatory information

See Section 16 for hazard class, hazard statements and risk phrase description

**Section 4 First Aid Measures****4.1 Description of first aid measures****Inhalation**

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

**Eye Contact**

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

**Skin Contact**

In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

**Ingestion**

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

**SAFETY DATA SHEET**

Doc. ID: 395185 AE

Revised (year/month/day) 2015/04/15

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## Section 4 First Aid Measures (Continued)

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

Causes serious eye damage.  
Causes skin irritation.  
May be harmful if swallowed  
See Section 11 Toxicological Information for more detailed health information.

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

No specific medical attention or treatment required.

## Section 5 Fire Fighting Measures

**Flammable Properties**

Flammable liquid and vapor.

**5.1 Extinguishing Media**

Dry chemical, carbon dioxide or alcohol resistant foam. Use water spray to cool containers exposed to fire.

**5.2 Special hazards arising from the substance or mixture****Special Fire and Explosion Hazards**

Vapors form explosive mixtures with air above flash point. Vapors are heavier than air; fire may flash from ignition source back along vapor trail.

**Hazardous Combustion Products**

Oxides of carbon

**5.3 Advice for fire fighters****Protective Equipment**

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

**5.4 Additional information**

No further relevant information available.

## Section 6 Accidental Release Measures

**6.1 Personal precautions, protective equipment and emergency procedures****Personal Precautions**

Observe general safety guidelines for protection; avoid eye and skin contact.  
Wear protective gloves, protective clothing and eye/face protection.

**6.2 Environmental Precautions**

Contain spill to prevent migration or evaporation.  
Do not allow the undiluted product to enter sewers/surface or ground water.  
Dispose of contents/container in accordance with local regulations

**6.3 Methods and material for containment and cleaning up****Spill and Leak Procedures**

Ventilate area. Remove all sources of ignition. Contain spill and collect with inert absorbent and place in a suitable container for disposal.  
Dispose of all waste material in accordance with local guidelines.

**6.4 Reference to other sections**

Refer sections 8 and 13.

**SAFETY DATA SHEET**
 Doc. ID: 395185 AE  
 Revised (year/month/day) 2015/04/15

## Section 7 Handling and Storage

- 7.1 Precautions for safe handling** Use good laboratory procedures; avoid eye and skin contact.  
Avoid inhalation of vapor or mist.
- 7.2 Conditions for safe storage, including any incompatibilities**  
Store at 15 to 30°C, as directed on the product label.  
To maintain product quality, store according to the instructions in the product labeling.  
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).
- 7.3 Specific end uses** No further relevant information available.

## Section 8 Exposure Controls and Personal Protection

### 8.1 Control parameters

**Exposure Limits****US OSHA**

Ethyl Alcohol CAS # 64-17-5	1000 ppm TWA; 1900 mg/m <sup>3</sup> TWA
Isopropyl Alcohol CAS # 67-63-0	400 ppm TWA; 980 mg/m <sup>3</sup> TWA
Hydrogen Peroxide CAS # 7722-84-1	1 ppm TWA; 1.4 mg/m <sup>3</sup> TWA

**ACGIH**

Ethyl Alcohol CAS # 64-17-5	1000 ppm STEL
Isopropyl Alcohol CAS # 67-63-0	400 ppm STEL; 200 ppm TWA
Hydrogen Peroxide CAS # 7722-84-1	1 ppm TWA

**DFG MAK**

Ethyl Alcohol CAS # 64-17-5	1000 ppm Peak; 1920 mg/m <sup>3</sup> Peak; 500 ppm TWA MAK; 960 mg/m <sup>3</sup> TWA MAK
Isopropyl Alcohol CAS # 67-63-0	400 ppm Peak; 1000 mg/m <sup>3</sup> Peak; 200 ppm TWA MAK; 500 mg/m <sup>3</sup> TWA MAK
Hydrogen Peroxide CAS # 7722-84-1	0.5 ppm Peak; 0.71 mg/m <sup>3</sup> Peak; 0.5 ppm TWA MAK; 0.71 mg/m <sup>3</sup> TWA MAK

**Ireland**

Ethyl Alcohol CAS # 64-17-5	1000 ppm STEL
Isopropyl Alcohol CAS # 67-63-0	200 ppm TWA; 400 ppm STEL; Potential for cutaneous absorption
Hydrogen Peroxide CAS # 7722-84-1	1 ppm TWA; 1.5 mg/m <sup>3</sup> TWA; 2 ppm STEL; 3 mg/m <sup>3</sup> STEL

**IOELVs**

None established

**SAFETY DATA SHEET**
 Doc. ID: 395185 AE  
 Revised (year/month/day) 2015/04/15

## Section 8 Exposure Controls and Personal Protection (Continued)

**NIOSH**

Ethyl Alcohol CAS # 64-17-5	3300 ppm IDLH (10% LEL); 1000 ppm TWA; 1900 mg/m <sup>3</sup> TWA
Isopropyl Alcohol CAS # 67-63-0	2000 ppm IDLH (10% LEL); 500 ppm STEL; 1225 mg/m <sup>3</sup> STEL; 400 ppm TWA; 980 mg/m <sup>3</sup> TWA
Hydrogen Peroxide CAS # 7722-84-1	75 ppm IDLH; 1 ppm TWA; 1.4 mg/m <sup>3</sup> TWA

**Japan**

None established

**8.2 Exposure controls****Engineering Controls**

No special engineering controls are required. Use with good general ventilation.

**Eye Protection**

Safety glasses or chemical goggles should be worn to prevent eye contact.  
 Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

**Skin Protection**

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.  
 Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

**Respiratory Protection**

Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

## Section 9 Physical and Chemical Properties

**9.1 Information on basic physical and chemical properties**

<b>Physical State</b>	Liquid	<b>Specific Gravity (Water=1.0)</b>	0.9 @20°C
<b>Color</b>	Colorless	<b>Solubility</b>	
<b>Transparency</b>	Clear	<b>Water</b>	Soluble
<b>Odor</b>	Alcohol odor	<b>Organic</b>	Not determined
<b>pH</b>	Not determined	<b>Partition coefficient: n-octanol/water</b>	Not determined
<b>Freezing Point</b>	Not determined	<b>Auto-ignition Temp.</b>	Not determined
<b>Boiling Point</b>	Not determined	<b>Decomposition Temperature</b>	Not determined
<b>Flash Point</b>	15.5°C (59.9°F)	<b>Percent Volatiles</b>	Not determined
<b>Evaporation Rate</b>	Not determined	<b>Vapor Pressure</b>	Not determined
<b>Flammability (Solid, Gas)</b>	Not applicable	<b>Viscosity</b>	Not determined
<b>Flammability Limits</b>	Not determined	<b>Explosive Properties</b>	Not applicable

**SAFETY DATA SHEET**
 Doc. ID: 395185 AE  
 Revised (year/month/day) 2015/04/15

## Section 9 Physical and Chemical Properties (Continued)

<b>Vapor Density</b>	Not determined	<b>Oxidizing Properties</b>	Not applicable
<b>Odor Threshold</b>	Ethyl Alcohol 180 ppm geometric mean air odor threshold = (detectable); 100 ppm geometric mean air odor threshold = (recognizable) Isopropyl Alcohol 43 ppm geometric mean air odor threshold = (detectable); 19 ppm geometric mean air odor threshold = (recognizable)		
<b>9.2 Other Information</b>	No further relevant information available.		

## Section 10 Stability and Reactivity

<b>10.1 Reactivity</b>	No further relevant information available.
<b>10.2 Chemical Stability</b>	The product is stable in accordance with recommended storage conditions.
<b>10.3 Possibility of hazardous reactions</b>	Avoid exposure to heat and incompatible materials.
<b>10.4 Conditions to Avoid</b>	To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.
<b>10.5 Incompatible materials</b>	Oxidizing agents
<b>10.6 Hazardous Decomposition Products</b>	When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

## Section 11 Toxicological Information

<b>11.1 Information on toxicological effects</b>	
<b>Toxicity Data for Hazardous Ingredients</b>	
Ethyl Alcohol CAS # 64-17-5	Oral LD50 Rat 7060 mg/kg; Inhalation LC50 Rat 124.7 mg/L 4 h
Isopropyl Alcohol CAS # 67-63-0	Inhalation LC50 Rat 72.6 mg/L 4 h; Oral LD50 Rat 4396 mg/kg; Dermal LD50 Rat 12800 mg/kg; Dermal LD50 Rabbit 12870 mg/kg
Hydrogen Peroxide CAS # 7722-84-1	Inhalation LC50 Rat 2 mg/L 4 h; Oral LD50 Rat 801 mg/kg; Dermal LD50 Rat 4060 mg/kg; Dermal LD50 Rabbit 2000 mg/kg
<b>Primary Routes of Exposure</b>	Eye contact, ingestion, inhalation, and skin contact.
<b>Skin Corrosion/Irritation</b>	Causes skin irritation.
<b>Serious eye damage/eye irritation</b>	Causes serious eye damage.
<b>Respiratory/skin sensitization</b>	No data available.
<b>Carcinogenicity</b>	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
<b>Germ cell mutagenicity</b>	No data available.

**SAFETY DATA SHEET**

Doc. ID: 395185 AE

Revised (year/month/day) 2015/04/15

## Section 11 Toxicological Information (Continued)

<b>Reproductive Toxicity</b>	No data available.
<b>Specific target organ toxicity – single exposure</b>	No data available.
<b>Specific target organ toxicity – repeated exposure</b>	No data available.
<b>Aspiration hazard</b>	No data available.
<b>Other Information</b>	May be harmful if swallowed

## Section 12 Ecological Information

### 12.1 Ecotoxicity

#### Fresh Water Species

Ethyl Alcohol CAS # 64-17-5	96 h LC50 Oncorhynchus mykiss: 12.0 - 16.0 mL/L [static]; 96 h LC50 Pimephales promelas: >100 mg/L [static]; 96 h LC50 Pimephales promelas: 13400 - 15100 mg/L [flow-through]
Isopropyl Alcohol CAS # 67-63-0	96 h LC50 Pimephales promelas: 9640 mg/L [flow-through]; 96 h LC50 Pimephales promelas: 11130 mg/L [static]; 96 h LC50 Lepomis macrochirus: >1400000 µg/L
Hydrogen Peroxide CAS # 7722-84-1	96 h LC50 Pimephales promelas: 16.4 mg/L; 96 h LC50 Lepomis macrochirus: 18-56 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 10.0-32.0 mg/L [static]
<b>Microtox</b>	No information available.

#### Water Flea

Ethyl Alcohol CAS # 64-17-5	48 h LC50 Daphnia magna: 9268 - 14221 mg/L; 24 h EC50 Daphnia magna: 10800 mg/L; 48 h EC50 Daphnia magna: 2 mg/L [Static]
Isopropyl Alcohol CAS # 67-63-0	48 h EC50 Daphnia magna: 13299 mg/L
Hydrogen Peroxide CAS # 7722-84-1	24 h EC50 Daphnia magna: 7.7 mg/L; 48 h EC50 Daphnia magna: 18 - 32 mg/L [Static]

#### Fresh Water Algae

Isopropyl Alcohol CAS # 67-63-0	96 h EC50 Desmodesmus subspicatus: >1000 mg/L; 72 h EC50 Desmodesmus subspicatus: >1000 mg/L
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**12.2 Persistence and degradability** Not determined for the product.

**12.3 Bioaccumulation** Not determined for the product.

**12.4 Mobility in soil** Not determined for the product.

**SAFETY DATA SHEET**
 Doc. ID: 395185 AE  
 Revised (year/month/day) 2015/04/15

## Section 12 Ecological Information (Continued)

**12.5 Results of PBT and vPvB assessment**

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

**12.6 Other Adverse Effects**

No further relevant information available.

## Section 13 Disposal Considerations

**13.1 Waste treatment methods****Product Waste Disposal**

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

**Package disposal**

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

**13.2 Additional information**

Suggested European waste catalogue 18 01 06\* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

## Section 14 Transport Information

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
<b>14.1 UN/ID Number</b>	1987	1987	1987	1987	PIN - 1987
<b>14.2 Shipping Name</b>	Alcohols, n.o.s. (Ethanol, Isopropanol solution)				
<b>14.3 Hazard Class</b>	3 Flammable Liquids	3 Flammable liquids	3 ORM-D Consumer Commodity	3 Flammable Liquids	3 Flammable Liquids
<b>Subsidiary Risk</b>	None	None	None	None	None
<b>Classification Code</b>	Not applicable	Not applicable	Not applicable	F1	Not applicable
<b>14.4 Packing Group</b>	II	II	II	II	II
<b>Special Provisions</b>	A3, A180	274	172	274	16
<b>Additional information</b>					
<b>IATA ERG Code</b>	3L	Not applicable	Not applicable	Not applicable	Not applicable
<b>EmS</b>	Not applicable	F-E, S-D	Not applicable	Not applicable	Not applicable
<b>NAERG Code</b>	Not applicable	Not applicable	127	Not applicable	127
<b>14.5 Environmental Hazards</b>					
<b>Marine Pollutant</b>	Not applicable	No	Not applicable	Not applicable	Not applicable

**SAFETY DATA SHEET**

Doc. ID: 395185 AE

Revised (year/month/day) 2015/04/15

**Section 14 Transport Information (Continued)**

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
<b>14.6 Special Precautions for user</b>					
Warning: Flammable liquid.					
<b>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>					
Not applicable					

**Section 15 Regulatory Information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****US Federal and State Regulations**

**SARA 313** Isopropyl Alcohol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

**California Proposition 65** No ingredients listed.

**Massachusetts MSL** Ethyl Alcohol is listed.  
Isopropyl Alcohol is listed.  
Hydrogen Peroxide is listed.

**New Jersey Dept. of Health RTK List**

Ethyl Alcohol is listed.  
Isopropyl Alcohol is listed.  
Hydrogen Peroxide is listed.

**Pennsylvania RTK** Ethyl Alcohol is listed.  
Isopropyl Alcohol is listed.  
Hydrogen Peroxide is listed.

**EU Regulations**

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

**Water Hazard Class (Germany) WGK 1**, low water endangering

**REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.**

No ingredients listed.

**According to EC Directives (1999/45/EC and 67/548 EEC)**

Highly flammable

F

**Risk and Safety Phrases**

R11 Highly flammable.  
S16 Keep away from sources of ignition - No smoking.  
S7 Keep container tightly closed.

**Canada**

This product is exempt from WHMIS label and SDS requirements.

**PIN** 1987



**SAFETY DATA SHEET**

Doc. ID: 395185 AE

Revised (year/month/day) 2015/04/15

**Section 15 Regulatory Information (Continued)****Ingredients on Ingredient Disclosure List**

Ethyl Alcohol  
Isopropyl Alcohol  
Hydrogen Peroxide

**Ingredients with unknown toxicological properties**

Product is exempt

**15.2 Chemical Safety Assessment** A Chemical Safety Assessment has not been carried out.

*Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.*

**Section 16 Other Information****Beckman Coulter Safety Rating**

**Flammability: 3**  
**Health: 2**  
**Reactivity with Water: 1**  
**Contact: 2**

Code  
0=None  
1=Slight  
2=Caution  
3=Severe

**Revision Changes**

Updated to GHS.

**Hazard Class, hazard statements and risk phrase description from section 3**

C - Corrosive  
F - Highly flammable  
O - Oxidising  
Xi - Irritant  
R11 Highly flammable.  
R35 Causes severe burns.  
R20/22 Harmful by inhalation and if swallowed.  
R36 Irritating to eyes.  
R67 Vapours may cause drowsiness and dizziness.  
R5 Heating may cause an explosion.  
R8 Contact with combustible material may cause fire.  
Acute Tox. Inhal. 4 - Acute Toxicity Inhalation, Category 4  
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4  
Eye Dam. 1 - Eye Damage Category 1  
Eye Irrit. 2 - Eye Irritation Category 2  
Flam. Liq. 2 - Flammable Liquids, Category 2  
Ox. Liq. 1 - Oxidizing Liquids Category 1  
Skin Corr. 1A - Skin Corrosion Category 1A  
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3  
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3  
H225 - Highly flammable liquid and vapour.  
H271 - May cause fire or explosion; strong oxidiser.  
H302 - Harmful if swallowed.  
H314 - Causes severe skin burns and eye damage.  
H318 - Causes serious eye damage.

**SAFETY DATA SHEET**

Doc. ID: 395185 AE

Revised (year/month/day) 2015/04/15

**Section 16 Other Information (Continued)****Abbreviations and Acronyms**

H319 - Causes serious eye irritation.  
 H332 - Harmful if inhaled.  
 H335 - May cause respiratory irritation.  
 H336 - May cause drowsiness or dizziness.  
 ACGIH - American Conference of Governmental Industrial Hygienists  
 ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road  
 CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act  
 CLP - Classification, Labeling and Packaging  
 DFGMAK - Republic Germany's maximum exposure limit  
 GHS - Globally Harmonized System  
 HCS - Hazard Communication Standard  
 IARC - International Agency for Research on Cancer  
 IATA - International Air Transport Association  
 ICAO - International Civil Aviation Organization  
 IMDG - International Maritime Dangerous Goods  
 IOELVs - European Unions' Indicative Occupational Exposure Limit Values  
 NIOSH - National Institute for Occupational Safety and Health  
 NTP - National Toxicology Program  
 OSHA - Occupational Safety and Health Administration  
 PBT - Persistent bioaccumulative and toxic substances  
 SARA - Superfund Amendments and Reauthorization Act  
 TDG - Canadian Transportation Of Dangerous Goods Regulations.  
 UN GHS - United Nations Globally Harmonized System  
 US DOT - United States Department of Transportation  
 WHMIS - Workplace Hazardous Material Information System  
 vPvB - Very persistent and very bioaccumulative substances  
 LC50 - Lethal Concentration, 50%  
 LD50 - Lethal Dose, 50%

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# SAFETY DATA SHEET

## 1. Identification

**Product identifier** HEPATYRIX

**Other means of identification**  
**Synonyms**

COMBINED INACTIVATED HEPATITIS A AND PURIFIED VI POLYSACCHARIDE TYPHOID VACCINE

**Recommended use** Medicinal Product

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

**Recommended restrictions** No other uses are advised.

**Manufacturer/Importer/Supplier/Distributor information**

**Manufacturer**

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

## 2. Hazard(s) identification

**Classified hazards**

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

**Label elements**

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

**Hazard(s) not otherwise classified (HNOC)**

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

## 3. Composition/information on ingredients

**Mixtures**

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

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

## 4. First-aid measures

**Inhalation**

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

**Skin contact**

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

**Eye contact**

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

**Ingestion**

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

<b>Most important symptoms/effects, acute and delayed</b>	None known.
<b>Indication of immediate medical attention and special treatment needed</b>	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.
<b>General information</b>	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

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

## 6. Accidental release measures

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

## 7. Handling and storage

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

## 8. Exposure controls/personal protection

<b>Occupational exposure limits</b>	
<b>GSK</b>	
Not established	
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	No particular ventilation requirements.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Hand protection</b>	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.
<b>Skin protection</b>	
<b>Other</b>	Wear appropriate chemical resistant clothing.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required.

<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	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

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

### Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

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

## 11. Toxicological information

### Information on likely routes of exposure

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

<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use.
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	None known.
<b>Information on toxicological effects</b>	
<b>Acute toxicity</b>	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.
<b>Serious eye damage/eye irritation</b>	Health injuries are not known or expected under normal use. Due to partial or complete lack of data the classification is not possible.
<b>Respiratory or skin sensitization</b>	
<b>Respiratory sensitization</b>	Not available.
<b>Skin sensitization</b>	None known.
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>Carcinogenicity</b>	Due to partial or complete lack of data the classification is not possible.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	
Not listed.	
<b>Reproductive toxicity</b>	Due to partial or complete lack of data the classification is not possible.
<b>Specific target organ toxicity - single exposure</b>	None known.
<b>Specific target organ toxicity - repeated exposure</b>	None known.
<b>Aspiration hazard</b>	Not likely, due to the form of the product.
<b>Further information</b>	Caution - Pharmaceutical agent.

## 12. Ecological information

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

## 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	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

<b>DOT</b>	Not regulated as a dangerous good.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.

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

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

## 15. Regulatory information

### US federal regulations

One or more components are not listed on TSCA.

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

Not regulated.

#### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

#### SARA 304 Emergency release notification

Not regulated.

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

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### Hazard categories

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

#### SARA 302 Extremely hazardous substance

Not listed.

#### SARA 311/312 Hazardous chemical

No

#### SARA 313 (TRI reporting)

Not regulated.

### Other federal regulations

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

Not regulated.

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

Not regulated.

#### Safe Drinking Water Act (SDWA)

Not regulated.

### US state regulations

#### US. Massachusetts RTK - Substance List

Not regulated.

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

Not listed.

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

Not listed.

#### US. Rhode Island RTK

Not regulated.

#### US. California Proposition 65

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

### International Inventories

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

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

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

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

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

<b>Issue date</b>	06-24-2014
<b>Revision date</b>	06-24-2014
<b>Version #</b>	10
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 1 Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	Health: 1 Flammability: 0 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.
<b>Revision Information</b>	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Regulatory Information: United States





## SAFETY DATA SHEET

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- |  |                           |  |
|--|---------------------------|--|
| <b>1.1 Product identifier</b>  | Trade name                | Influenza A & B Test, Dipstick   |
| <b>1.2 Relevant identified uses of the substance or mixture and uses advised against</b> | Identified use(s)         | <i>In vitro</i> diagnostic reagent. For professional use only.                     |
| <b>1.3 Details of the supplier of the safety data sheet</b>                              | Company Identification    | Alere Scarborough Inc.,<br>10 Southgate Road,<br>Scarborough,<br>Maine 04074, USA. |
|  | Telephone                 | +1 207-730-5750  |
|  | E-Mail (competent person) | ts.scr@alere.com   |
| <b>1.4 Emergency telephone number</b>  | Emergency Phone No.       | +1 207-730-5750  |

### ► SECTION 2: HAZARDS IDENTIFICATION

- |   |   |                              |
|---|---|------------------------------|
| <b>2.1 Classification of the substance or mixture</b> | OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS | Not classified as hazardous. |
| <b>2.2 Label elements</b>                             |   | Not applicable.              |
| <b>2.3 Other hazards</b>                              |   | None anticipated.            |

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- |                     |                       |  |
|---------------------|-----------------------|--|
| <b>3.2 Mixtures</b> | Description:          | <i>In vitro</i> diagnostic reagent. Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents. |
|                     | Dangerous components: | The product does not contain reportable quantities of dangerous components.  |

### SECTION 4: FIRST AID MEASURES



- |  |                     |   |
|--|---------------------|---|
| <b>4.1 Description of first aid measures</b> | General information | The following first aid measures are not expected to be required unless there is severe misuse of the product |
|  | Inhalation          | Supply fresh air; consult doctor in case of complaint.  |
|  | Skin Contact        | Wash skin with soap and water.  |
|  | Eye Contact         | Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.                       |
|  | Ingestion           | Wash out mouth with water. Consult a doctor.  |



## SAFETY DATA SHEET

- |            |   |       |
|------------|---|-------|
| <b>4.2</b> | <b>Most important symptoms and effects, both acute and delayed</b>                | None. |
| <b>4.3</b> | <b>Indication of the immediate medical attention and special treatment needed</b> | None. |

### SECTION 5: FIRE-FIGHTING MEASURES

- |            |  |   |
|------------|--|---|
| <b>5.1</b> | <b>Extinguishing media</b><br>Suitable Extinguishing Media   | CO <sub>2</sub> , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.   |
| <b>5.2</b> | <b>Special hazards arising from the substance or mixture</b> | In case of fire, the following can be released: Carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> ),   |
| <b>5.3</b> | <b>Advice for fire-fighters</b>                              | Use fire-extinguishing methods suitable to surrounding conditions.<br>Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires. |

### SECTION 6: ACCIDENTAL RELEASE MEASURES

- |            |  |  |
|------------|--|--|
| <b>6.1</b> | <b>Personal precautions, protective equipment and emergency procedures</b> | Refer to Section 8 for protective measures when handling the spillage. |
| <b>6.2</b> | <b>Environmental precautions</b>   | No special requirements.   |
| <b>6.3</b> | <b>Methods and material for containment and cleaning up</b>                | Collect material and dispose of as waste according to Section 13.      |
| <b>6.4</b> | <b>Reference to other sections</b>   | 8, 13  |

### SECTION 7: HANDLING AND STORAGE

- |            |   |   |
|------------|---|---|
| <b>7.1</b> | <b>Precautions for safe handling</b>                                | Specimens should be handled as potentially infectious materials. Refer to Regulation 29 CFR 1910.1030 for information on handling biohazardous materials.<br>Avoid contact with skin and eyes.<br>Keep out of reach of children.<br>Wash hands and exposed skin after use.<br>Clean work areas with hypochlorite or other disinfecting agent. |
| <b>7.2</b> | <b>Conditions for safe storage, including any incompatibilities</b> | Store in the original container at 4 to 30°C.   |
| <b>7.3</b> | <b>Specific end use(s)</b>  | Use as per instructions for use.  |

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- |              |   |  |
|--------------|---|--|
| <b>8.1</b>   | <b>Control parameters</b>               |  |
| <b>8.1.1</b> | <b>Occupational Exposure Limits</b>     | The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. |
| <b>8.2</b>   | <b>Exposure controls</b>                |  |
| <b>8.2.1</b> | <b>Appropriate engineering controls</b> | Not relevant for this material.  |
| <b>8.2.2</b> | <b>Personal protection equipment</b>    |  |
|              | Eye/face protection                     | Not normally required.   |
|              | Hand protection (Hygiene Measures)      | Disposable gloves.   |



## SAFETY DATA SHEET



Material of gloves:

Latex / natural rubber, Nitrile rubber.

Penetration time of glove material:

Gloves resistance is not critical when the product is handled according to the instructions for use.

Body protection

Laboratory coat.

Respiratory protection

### 8.2.3 Environmental Exposure Controls

No special measures are required.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance

Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.

Color

White.

Odor

No odor.

Odor Threshold (ppm)

Not applicable.

pH (Value)

Not determined.

Melting Point (°C) / Freezing Point (°C)

Not available.

Boiling point/boiling range (°C):

Not applicable.

Flash Point (°C)

Not applicable

Evaporation rate (BA = 1)

Not applicable.

Flammability (solid, gas)

Not determined.

Explosive limit ranges

Not applicable.

Vapor Pressure (Pascal)

Not applicable.

Vapor Density (Air=1)

Not applicable.

Density (g/ml)

Not determined.

Solubility (Water)

Not applicable.

Solubility (Other)

Not determined.

Partition Coefficient (n-Octanol/water)

Not determined.

Auto Ignition Temperature (°C)

Not determined.

Decomposition Temperature (°C)

Not determined.

Viscosity (mPa.s)

Not applicable.

Explosive properties

Not explosive.

Oxidizing properties

Not oxidizing.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

None known.

### 10.2 Chemical stability

The product is stable in accordance with the recommended storage conditions.

### 10.3 Possibility of hazardous reactions

Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerization will not occur.

### 10.4 Conditions to avoid

None.

### 10.5 Incompatible materials

Strong Acids.

### 10.6 Hazardous Decomposition Product(s)

None known.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects



## SAFETY DATA SHEET

### 11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Irritation	Based upon the available data, the classification criteria are not met.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitization	Based upon the available data, the classification criteria are not met.
Repeated dose toxicity	No data
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	No data
Toxicity for reproduction	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

### Health Effects and Symptoms

Skin Contact	No significant harmful effects anticipated.
Eye Contact	No significant harmful effects anticipated.
Ingestion	No significant harmful effects anticipated.

### 11.2 Other information

Not applicable

## SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2 Persistence and degradability	The product is likely to persist in the environment.
12.3 Bioaccumulative potential	The product has low potential for bioaccumulation.
12.4 Mobility in soil	No data.
12.5 Results of PBT and vPvB assessment	Not applicable
12.6 Other adverse effects	Not applicable

## SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product:	Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Packaging:	Disposal should be in accordance with applicable federal, state and local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service



## SAFETY DATA SHEET

providers for further information.

### SECTION 14: TRANSPORT INFORMATION

14.1	UN number	Not applicable
14.2	Proper Shipping Name	Not applicable
14.3	Transport hazard class(es)	Not classified as dangerous for transport.
14.4	Packing Group	Not applicable
14.5	Environmental hazards	Not applicable
14.6	Special precautions for user	Not applicable
14.7	Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

### SECTION 15: REGULATORY INFORMATION

15.1	<b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809
	<b>Chemical inventory listings relevant to US regulations</b>	
	<b>Carcinogen listings</b>	
	IARC:	None of the ingredients is listed.
	NTP:	None of the ingredients is listed.
	ACGIH:	None of the ingredients is listed.
	OSHA:	None of the ingredients is listed.
	EPA	None of the ingredients is listed.
	<b>Californian Proposition 65</b>	
	Chemicals known to cause cancer:	None of the ingredients is listed.
	Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.
	<b>SARA</b>	
	Section 355 (extremely hazardous substances):	Sodium azide (< 1.0%)
	Section 313 (specific toxic chemical listings):	Sodium azide (< 0.1%)
15.2	<b>Chemical Safety Assessment</b>	Not applicable.

### SECTION 16: OTHER INFORMATION

#### LEGEND

STOT Specific Target Organ Toxicity

#### Additional Information

Reason for update: Update in accordance with GHS.  
Changes to section 2  
► Indicates altered section  
Supersedes: Version: 1

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

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



## SAFETY DATA SHEET

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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.



## 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<sup>®</sup>, Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)

Adacel<sup>®</sup>, Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed

DAPTACEL<sup>®</sup>, Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

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

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

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

Imogam<sup>®</sup> Rabies-HT, Rabies Immune Globulin (Human) USP, Heat Treated

IMOVAX<sup>®</sup> RABIES, Rabies Vaccine

IPOL<sup>®</sup>, Poliovirus Vaccine Inactivated

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

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

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

TENIVAC<sup>™</sup>, Tetanus and Diphtheria Toxoids Adsorbed

Tetanus Toxoid Adsorbed

TheraCys<sup>®</sup>, BCG Live (Intravesical)

TUBERSOL<sup>®</sup>, Tuberculin Purified Protein Derivative (Mantoux)

Typhim Vi<sup>®</sup>, Typhoid Vi Polysaccharide Vaccine

YF-VAX<sup>®</sup>, Yellow Fever Vaccine

**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.**

Sanofi Pasteur Inc. provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. Individuals receiving this information must exercise their independent judgment in determining its appropriateness for a particular purpose. Sanofi Pasteur Inc. makes no representations, or warranties, either express or implied, of merchantability, fitness for a particular purpose with respect to the information set forth herein or to the product to which the information refers. Accordingly, Sanofi Pasteur Inc. will not be responsible for damages resulting from use of or reliance upon this information.





## SAFETY DATA SHEET (SDS)

407 New Sanford Road  
La Vergne, TN 37086

### Isopropyl Rubbing Alcohol USP 70%

SDS Revision Date:

02/24/2015

## 1. Identification

### 1.1. Product identifier

**Product Identity**

Isopropyl Rubbing Alcohol USP 70%

**Alternate Names**

Product Code: P907016, P907032, P907128

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

**Intended use**

First aid to help prevent the risk of infection in: minor cuts, scrapes, burns. For external use only.

**Application Method**

Clean the affected area. Apply 1 to 3 times daily.

### 1.3. Details of the supplier of the safety data sheet

**Company Name**

NDC, Inc.  
407 New Sanford Rd.  
Laverne, TN 37086

**Emergency**

**Chemtrec 24 hour Emergency Telephone No.**

800-424-9300

**Customer Service:**

800-421-3040

## 2. Hazard(s) identification

### 2.1. 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.

### 2.2. 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.

## Safety Data Sheet

### Isopropyl Rubbing Alcohol USP 70%

**SDS Revision Date:**

**02/24/2015**

**[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.

### 3. Composition/information on ingredients

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

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Isopropyl Alcohol CAS Number: 0000067-63-0	50 - 75	Flam. Liq. 2;H225 Eye Irrit. 2;H319 STOT SE 3;H336	[1][2]

[1] Substance classified with a health or environmental hazard.

[2] Substance with a workplace exposure limit.

[3] PBT-substance or vPvB-substance.

\*The full texts of the phrases are shown in Section 16.

## Safety Data Sheet

### Isopropyl Rubbing Alcohol USP 70%

SDS Revision Date:

02/24/2015

#### 4. First aid measures

##### 4.1. Description of first aid measures

<b>General</b>	In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person.
<b>Inhalation</b>	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.
<b>Eyes</b>	Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.
<b>Skin</b>	Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.
<b>Ingestion</b>	If swallowed obtain immediate medical attention. Keep at rest. Do NOT induce vomiting.

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

<b>Overview</b>	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.
<b>Inhalation</b>	May cause drowsiness or dizziness.
<b>Eyes</b>	Causes serious eye irritation.

#### 5. Fire-fighting measures

##### 5.1. Extinguishing media

Recommended extinguishing media; alcohol resistant foam, CO<sub>2</sub>, water fog.  
Do not use; water jet.

## Safety Data Sheet

### Isopropyl Rubbing Alcohol USP 70%

SDS Revision Date:

02/24/2015

**5.2. 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.

**5.3. Advice for fire-fighters**

Dilution of burning liquid with water will affect extinguishment.

None

ERG Guide No. ----

## 6. Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**

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

**6.2. Environmental precautions**

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

**6.3. Methods and material for containment and cleaning up**

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.

## 7. Handling and storage

**7.1. Precautions for safe handling**

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

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

**7.2. Conditions for safe storage, including any incompatibilities**

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.

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

**7.3. Specific end use(s)**

No data available.

## Safety Data Sheet

### Isopropyl Rubbing Alcohol USP 70%

SDS Revision Date:

02/24/2015

## 8. Exposure controls and personal protection

### 8.1. Control parameters

#### Exposure

CAS No.	Ingredient	Source	Value
0000067-63-0	Isopropyl Alcohol	OSHA	TWA 400 ppm (980 mg/m <sup>3</sup> ) STEL 500 ppm
		ACGIH	TWA: 200 ppm STEL: 400 ppm Revised 2003,
		NIOSH	TWA 400 ppm (980 mg/m <sup>3</sup> ) ST 500 ppm (1225 mg/m <sup>3</sup> )
		Supplier	No Established Limit

#### Carcinogen Data

CAS No.	Ingredient	Source	Value
0000067-63-0	Isopropyl Alcohol	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: Yes; Group 4: No;

### 8.2. Exposure controls

#### Respiratory

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

#### Eyes

Protective goggles if desired.

#### Skin

Rubber or vinyl gloves if desired.

#### Engineering Controls

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

#### Other Work Practices

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

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

## 9. Physical and chemical properties

#### Appearance

Colorless Liquid

#### Odor

Characteristic

#### Odor threshold

Not Measured

#### pH

Not Measured

#### Melting point / freezing point

Not Measured

#### Initial boiling point and boiling range

87C

#### Flash Point

77F (TCC)

## Safety Data Sheet

### Isopropyl Rubbing Alcohol USP 70%

SDS Revision Date:

02/24/2015

Evaporation rate (Ether = 1)	2.3 (Butyl Acetate=1)
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: 2 Upper Explosive Limit: 12
Vapor pressure (Pa)	33 mmHg
Vapor Density	2.07 (Air=1)
Specific Gravity	0.88 (H <sub>2</sub> O=1) @ 25 C
Solubility in Water	Complete
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not Measured
Decomposition temperature	Not Measured
Viscosity (cSt)	Not Measured
% Volatile	100
Isopropyl Alcohol Assay by Volume	68%-72%

#### 9.2. Other information

No other relevant information.

## 10. Stability and reactivity

#### 10.1. Reactivity

Hazardous Polymerization will not occur.

#### 10.2. Chemical stability

Stable under normal circumstances.

#### 10.3. Possibility of hazardous reactions

No data available.

#### 10.4. Conditions to avoid

Avoid heat, sparks and open flame.

#### 10.5. Incompatible materials

Anyhydride, isocyanate, monomer and organo-metallic.

#### 10.6. Hazardous decomposition products

Burning may produce carbon monoxide and carbon dioxide contamination.

## Safety Data Sheet

### Isopropyl Rubbing Alcohol USP 70%

SDS Revision Date:

02/24/2015

## 11. 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	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
Isopropyl Alcohol - (67-63-0)	4,710.00, Rat - Category: 5	12,800.00, Rat - Category: NA	72.60, Rat - Category: NA	No data available	No data available

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

## Safety Data Sheet

### Isopropyl Rubbing Alcohol USP 70%

SDS Revision Date:

02/24/2015

## 12. Ecological information

### 12.1. Toxicity

The preparation has been assessed following the conventional method of the Dangerous Preparations Directive 1999/45/EC and GHS and is not classified as dangerous for the environment, but contains substance(s) dangerous for the environment. See section 3 for details

### Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
Isopropyl Alcohol - (67-63-0)	1,400.00, <i>Lepomis macrochirus</i>	100.00, <i>Daphnia magna</i>	100.00 (72 hr), <i>Scenedesmus subspicatus</i>

### 12.2. Persistence and degradability

There is no data available on the preparation itself.

### 12.3. Bioaccumulative potential

Not Measured

### 12.4. Mobility in soil

No data available.

### 12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

### 12.6. Other adverse effects

No data available.

## 13. Disposal considerations

### 13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

## 14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number			
14.2. UN proper shipping name			
14.3. Transport hazard class(es)	DOT Hazard Class: DOT Label:	IMDG: Sub Class:	Air Class:
14.4. Packing group			



## Safety Data Sheet

### Isopropyl Rubbing Alcohol USP 70%

SDS Revision Date:

02/24/2015

**14.5. Environmental hazards****IMDG**

Marine Pollutant:

**14.6. Special precautions for user**
**15. Regulatory information**
**Regulatory Overview**

The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

**Toxic Substance Control Act ( TSCA)**

All components of this material are either listed or exempt from listing on the TSCA Inventory.

**WHMIS Classification**

B2 D2B

**US EPA Tier II Hazards****Fire:** Yes**Sudden Release of Pressure:** No**Reactive:** No**Immediate (Acute):** Yes**Delayed (Chronic):** No**EPCRA 311/312 Chemicals and RQs:**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**EPCRA 302 Extremely Hazardous:**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**EPCRA 313 Toxic Chemicals:**

Isopropyl Alcohol

**Proposition 65 - Carcinogens (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Developmental Toxins (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Female Repro Toxins (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

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

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**New Jersey RTK Substances (>1%):**

Isopropyl Alcohol

**Pennsylvania RTK Substances (>1%):**

Isopropyl Alcohol

**Safety Data Sheet**  
**Isopropyl Rubbing Alcohol USP 70%**

SDS Revision Date:

02/24/2015

<b>16. Other information</b>
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The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

H225 Highly flammable liquid and vapor.

H319 Causes serious eye irritation.

H336 May cause drowsiness and dizziness.

**This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.**

Disclaimer: The contents of this MSDS are believed to be correct but do not purport to be all-inclusive and should only be used as a guide. NDC, Inc. disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from the reliance on the above information.

End of Document



## SAFETY DATA SHEET

Revision date: 03-Aug-2016

Version: 1.0

Page 1 of 12

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

#### Product Identifier

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

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

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

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

#### Details of the Supplier of the Safety Data Sheet

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

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

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

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

### 2. HAZARDS IDENTIFICATION

#### Classification of the Substance or Mixture

##### GHS - Classification

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

#### Label Elements

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

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

## SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP  
(Hospira Inc.)  
Revision date: 03-Aug-2016

Page 2 of 12

Version: 1.0

**Other Hazards**

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

**Note:**

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

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

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

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

**Additional Information:**

\* Proprietary

\*\* to adjust pH

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

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

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

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

**Skin Contact:**

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

## SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP  
(Hospira Inc.)  
Revision date: 03-Aug-2016

Page 3 of 12

Version: 1.0

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

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

**Most Important Symptoms and Effects, Both Acute and Delayed**

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

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

**5. FIRE FIGHTING MEASURES**

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

**Special Hazards Arising from the Substance or Mixture**

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

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

**Advice for Fire-Fighters**

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

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

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

**Environmental Precautions**

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

**Methods and Material for Containment and Cleaning Up**

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

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

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

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

**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store as directed by product packaging.

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

## SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP  
(Hospira Inc.)  
Revision date: 03-Aug-2016

Page 4 of 12

Version: 1.0

## 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 <sup>3</sup>
Austria OEL - MAKs	1000 ppm
	1900 mg/m <sup>3</sup>
Belgium OEL - TWA	1000 ppm
	1907 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1000 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1000 mg/m <sup>3</sup>
Denmark OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Estonia OEL - TWA	500 ppm
	1000 mg/m <sup>3</sup>
Finland OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
France OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	500 ppm
	960 mg/m <sup>3</sup>
Germany (DFG) - MAK	500 ppm
	960 mg/m <sup>3</sup>
Greece OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Hungary OEL - TWA	1900 mg/m <sup>3</sup>
Latvia OEL - TWA	1000 mg/m <sup>3</sup>
Lithuania OEL - TWA	500 ppm
	1000 mg/m <sup>3</sup>
Netherlands OEL - TWA	260 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	1000 ppm
	1900 mg/m <sup>3</sup>
Poland OEL - TWA	1900 mg/m <sup>3</sup>
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Russia OEL - TWA	1000 mg/m <sup>3</sup>
Slovakia OEL - TWA	500 ppm
	960 mg/m <sup>3</sup>
Slovenia OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Sweden OEL - TWAs	500 ppm
	1000 mg/m <sup>3</sup>
Switzerland OEL - TWAs	500 ppm
	960 mg/m <sup>3</sup>
Vietnam OEL - TWAs	1000 mg/m <sup>3</sup>

#### Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	2 ppm
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## SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP  
(Hospira Inc.)  
Revision date: 03-Aug-2016

Page 5 of 12

Version: 1.0

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

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

## SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP  
(Hospira Inc.)  
Revision date: 03-Aug-2016

Page 6 of 12

Version: 1.0

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

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

**Sodium chloride**

Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>

**Exposure Controls****Engineering Controls:**

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

**Personal Protective Equipment:**

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:**

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

**Eyes:**

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

**Skin:**

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

**Respiratory protection:**

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

**9. PHYSICAL AND CHEMICAL PROPERTIES****Physical State:**

Solution

**Color:**

Clear to light yellow

**Odor:**

Alcohol Slight

**Odor Threshold:**

No data available.

**Molecular Formula:**

Mixture

**Molecular Weight:**

Mixture

**Solvent Solubility:**

No data available

**Water Solubility:**

No data available

**Solubility:**

Soluble: Water

**pH:**

6.9-7.9

**Melting/Freezing Point (°C):**

No data available

**Boiling Point (°C):**

No data available.



## SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP  
(Hospira Inc.)  
Revision date: 03-Aug-2016

Page 7 of 12

Version: 1.0

**9. PHYSICAL AND CHEMICAL PROPERTIES**

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

**Sodium chloride**

No data available

**Ketorolac tromethamine**

No data available

**Ethanol**

No data available

**Water for injection**

No data available

**Hydrochloric Acid**

No data available

**Sodium hydroxide**

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Specific Gravity:** 0.991

**Viscosity:** No data available

**Flammability:**

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

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** 55 (ethanol)

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

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

**Polymerization:** Will not occur

**10. STABILITY AND REACTIVITY**

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions**

**Oxidizing Properties:** No data available

**Conditions to Avoid:** Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

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

**Hazardous Decomposition** No data available

**Products:**

**11. TOXICOLOGICAL INFORMATION**

**Information on Toxicological Effects**

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

**Short Term:** Accidental ingestion may cause effects similar to those seen in clinical use. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

## SAFETY DATA SHEET

**Material Name:** Ketorolac Tromethamine Injection, USP  
**(Hospira Inc.)**  
**Revision date:** 03-Aug-2016

Page 8 of 12

Version: 1.0

**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<sup>3</sup>  
 Rat Oral LD50 7,060mg/kg  
 Mouse Inhalation LC50 4h 39g/m<sup>3</sup>  
 Rat Inhalation LC50 10h 20,000ppm

**Sodium hydroxide**

Mouse IP LD50 40 mg/kg

**Irritation / Sensitization: (Study Type, Species, Severity)****Sodium chloride**

Eye Irritation Rabbit Moderate  
 Skin Irritation Rabbit Mild

**Ethanol**

Eye Irritation Rabbit Severe

**Hydrochloric Acid**

Skin Irritation Severe  
 Eye Irritation Severe

**Sodium hydroxide**

Eye Irritation Rabbit Severe  
 Skin Irritation Rabbit Severe

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

Reproductive & Fertility-Females Rat Oral 16 mg/kg/day NOAEL Negative  
 Reproductive & Fertility-Males Rat Oral 9 mg/kg/day NOAEL Negative  
 Prenatal & Postnatal Development Rabbit Oral 3.6 mg/kg/day NOAEL Negative  
 Prenatal & Postnatal Development Rat Oral 10 mg/kg/day NOAEL Negative

## SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP  
(Hospira Inc.)  
Revision date: 03-Aug-2016

Page 9 of 12

Version: 1.0

## 11. TOXICOLOGICAL INFORMATION

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

#### Ketorolac tromethamine

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

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

#### Ketorolac tromethamine

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

### Carcinogen Status:

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

#### Ethanol

IARC: Group 1 (Carcinogenic to Humans)

#### Hydrochloric Acid

IARC: Group 3 (Not Classifiable)

## 12. ECOLOGICAL INFORMATION

### Environmental Overview:

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

### Toxicity:

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

#### Ethanol

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

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

## SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP  
(Hospira Inc.)  
Revision date: 03-Aug-2016

Page 10 of 12

Version: 1.0

**13. DISPOSAL CONSIDERATIONS**

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

**14. TRANSPORT INFORMATION**

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

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

**15. REGULATORY INFORMATION**

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

**Ketorolac tromethamine**

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

**Ethanol**

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

**Hydrochloric Acid**

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

## SAFETY DATA SHEET

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

Page 11 of 12

Revision date: 03-Aug-2016

Version: 1.0

### 15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7
<b>Sodium hydroxide</b>	
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
<b>Water for injection</b>	
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
<b>Sodium chloride</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

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

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

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

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

**SAFETY DATA SHEET**

**Material Name:** Ketorolac Tromethamine Injection, USP  
(Hospira Inc.)  
**Revision date:** 03-Aug-2016

**Page 12 of 12****Version: 1.0**

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

**End of Safety Data Sheet**



## SAFETY DATA SHEET

Revision date: 27-Jul-2017

Version: 1.0

Page 1 of 11

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

#### Product Identifier

**Material Name:** Lidocaine hydrochloride and epinephrine injection, solution (Hospira, Inc.)

**Trade Name:** Not established  
**Synonyms:** Lignocaine with epinephrine  
**Chemical Family:** Not determined

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

**Intended Use:** Pharmaceutical product anesthetic agent

#### Details of the Supplier of the Safety Data Sheet

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

Hospira UK Limited

Horizon

Honey Lane

Hurley

Maidenhead, SL6 6RJ

United Kingdom

**Emergency telephone number:**

**CHEMTREC (24 hours): 1-800-424-9300**

**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**

**International CHEMTREC (24 hours): +1-703-527-3887**

### 2. HAZARDS IDENTIFICATION

#### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

#### Label Elements

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

#### Other Hazards

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

#### Note:

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

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

## SAFETY DATA SHEET

Material Name: Lidocaine hydrochloride and epinephrine  
injection, solution (Hospira, Inc.)  
Revision date: 27-Jul-2017

Page 2 of 11

Version: 1.0

**3. COMPOSITION / INFORMATION ON INGREDIENTS**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Epinephrine	51-43-4	200-098-7	Acute Tox. 2 (H300) Acute Tox. 2 (H310)	<= 0.002
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
Lidocaine Hydrochloride	73-78-9	200-803-8	Acute Tox.4 (H302)	<= 2
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**
Sodium metabisulfite USP	7681-57-4	231-673-0	Acute Tox. 4 (H302) Eye Dam. 1 (H318)	<0.1

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

**Additional Information:**

\* Proprietary

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

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

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

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

**Skin Contact:**

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

**Ingestion:**

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

**Inhalation:**

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

**Most Important Symptoms and Effects, Both Acute and Delayed****Symptoms and Effects of Exposure:**

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

**Medical Conditions**

None known

**Aggravated by Exposure:****Indication of the Immediate Medical Attention and Special Treatment Needed****Notes to Physician:**

None

**5. FIRE FIGHTING MEASURES****Extinguishing Media:**

Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**



## SAFETY DATA SHEET

Material Name: Lidocaine hydrochloride and epinephrine  
injection, solution (Hospira, Inc.)  
Revision date: 27-Jul-2017

Page 3 of 11

Version: 1.0

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

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

**Advice for Fire-Fighters**

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

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

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

**Environmental Precautions**

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

**Methods and Material for Containment and Cleaning Up**

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

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

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

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

**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

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

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

**HYDROCHLORIC ACID**

<b>ACGIH Ceiling Threshold Limit:</b>	2 ppm
<b>Australia PEAK</b>	5 ppm
	7.5 mg/m <sup>3</sup>
<b>Austria OEL - MAKs</b>	5 ppm
	8 mg/m <sup>3</sup>
<b>Belgium OEL - TWA</b>	5 ppm
	8 mg/m <sup>3</sup>
<b>Bulgaria OEL - TWA</b>	5 ppm
	8.0 mg/m <sup>3</sup>
<b>Cyprus OEL - TWA</b>	5 ppm
	8 mg/m <sup>3</sup>
<b>Czech Republic OEL - TWA</b>	8 mg/m <sup>3</sup>

## SAFETY DATA SHEET

Material Name: Lidocaine hydrochloride and epinephrine  
 injection, solution (Hospira, Inc.)  
 Revision date: 27-Jul-2017

Page 4 of 11

Version: 1.0

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

Estonia OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m <sup>3</sup>
Germany (DFG) - MAK	2 ppm 3.0 mg/m <sup>3</sup>
Greece OEL - TWA	5 ppm 7 mg/m <sup>3</sup>
Hungary OEL - TWA	8 mg/m <sup>3</sup>
Ireland OEL - TWAs	5 ppm 8 mg/m <sup>3</sup>
Italy OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Japan - OELs - Ceilings	2 ppm 3.0 mg/m <sup>3</sup>
Latvia OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Luxembourg OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Malta OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Netherlands OEL - TWA	8 mg/m <sup>3</sup>
Poland OEL - TWA	5 mg/m <sup>3</sup>
Portugal OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Romania OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Slovakia OEL - TWA	5 ppm 8.0 mg/m <sup>3</sup>
Slovenia OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Spain OEL - TWA	5 ppm 7.6 mg/m <sup>3</sup>
Switzerland OEL - TWAs	2 ppm 3.0 mg/m <sup>3</sup>
Vietnam OEL - TWAs	5 mg/m <sup>3</sup>
Sodium chloride	
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
SODIUM HYDROXIDE	
ACGIH Ceiling Threshold Limit:	2 mg/m <sup>3</sup>
Australia PEAK	2 mg/m <sup>3</sup>
Austria OEL - MAKs	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	2.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1 mg/m <sup>3</sup>
Estonia OEL - TWA	1 mg/m <sup>3</sup>
France OEL - TWA	2 mg/m <sup>3</sup>
Greece OEL - TWA	2 mg/m <sup>3</sup>

## SAFETY DATA SHEET

Material Name: Lidocaine hydrochloride and epinephrine  
injection, solution (Hospira, Inc.)  
Revision date: 27-Jul-2017

Page 5 of 11

Version: 1.0

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

Hungary OEL - TWA	2 mg/m <sup>3</sup>
Japan - OELs - Ceilings	2 mg/m <sup>3</sup>
Latvia OEL - TWA	0.5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	2 mg/m <sup>3</sup>
Poland OEL - TWA	0.5 mg/m <sup>3</sup>
Slovakia OEL - TWA	2 mg/m <sup>3</sup>
Slovenia OEL - TWA	2 mg/m <sup>3</sup>
Sweden OEL - TWAs	1 mg/m <sup>3</sup>
Switzerland OEL - TWAs	2 mg/m <sup>3</sup>

**Sodium metabisulfite USP**

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

**Epinephrine**

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

**Lidocaine Hydrochloride**

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

**Sodium chloride**

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

**Exposure Controls**

<b>Engineering Controls:</b>	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.
<b>Personal Protective Equipment:</b>	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.
<b>Hands:</b>	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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)

## SAFETY DATA SHEET

Material Name: Lidocaine hydrochloride and epinephrine  
injection, solution (Hospira, Inc.)  
Revision date: 27-Jul-2017

Page 6 of 11

Version: 1.0

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

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

**9. PHYSICAL AND CHEMICAL PROPERTIES**

<b>Physical State:</b>	Solution	<b>Color:</b>	Clear, colorless
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

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

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

**Water for injection**

No data available

**Sodium chloride**

No data available

**Sodium metabisulfite USP**

No data available

**SODIUM HYDROXIDE**

No data available

**HYDROCHLORIC ACID**

No data available

**Epinephrine**

No data available

**Lidocaine Hydrochloride**

No data available

**Decomposition Temperature (°C):** No data available.

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

**Flammability:**

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

**10. STABILITY AND REACTIVITY**

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	

## SAFETY DATA SHEET

Material Name: Lidocaine hydrochloride and epinephrine  
injection, solution (Hospira, Inc.)  
Revision date: 27-Jul-2017

Page 7 of 11

Version: 1.0

**10. STABILITY AND REACTIVITY**

<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	No data available

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

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

**Short Term:**

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

**Known Clinical Effects:**

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

**Acute Toxicity: (Species, Route, End Point, Dose)****Sodium chloride**

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

**HYDROCHLORIC ACID**

Rat Oral LD 50 238-277 mg/kg

**Epinephrine**

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

**Lidocaine Hydrochloride**

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

**Irritation / Sensitization: (Study Type, Species, Severity)****Sodium chloride**

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

**Lidocaine Hydrochloride**

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

## SAFETY DATA SHEET

Material Name: Lidocaine hydrochloride and epinephrine  
injection, solution (Hospira, Inc.)  
Revision date: 27-Jul-2017

Page 8 of 11

Version: 1.0

## 11. TOXICOLOGICAL INFORMATION

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

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

**Lidocaine Hydrochloride**

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

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

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vivo</i> Micronucleus	Rat	Negative

**Epinephrine**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Sister Chromatid Exchange	Negative with activation	
Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Equivocal without activation

**Lidocaine Hydrochloride**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative

**Carcinogen Status:**

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

**Sodium metabisulfite USP**

IARC:	Group 3 (Not Classifiable)
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**HYDROCHLORIC ACID**

IARC:	Group 3 (Not Classifiable)
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## 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
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<b>Toxicity:</b>	No data available
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<b>Persistence and Degradability:</b>	No data available
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<b>Bio-accumulative Potential:</b>	No data available
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<b>Mobility in Soil:</b>	No data available
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## SAFETY DATA SHEET

Material Name: Lidocaine hydrochloride and epinephrine  
 injection, solution (Hospira, Inc.)  
 Revision date: 27-Jul-2017

Page 9 of 11

Version: 1.0

**13. DISPOSAL CONSIDERATIONS****Waste Treatment Methods:**

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

**Epinephrine**

RCRA - P Series Wastes

Listed

**14. TRANSPORT INFORMATION**

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

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

**15. REGULATORY INFORMATION****Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture****Epinephrine**

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

**HYDROCHLORIC ACID**

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg

## SAFETY DATA SHEET

Material Name: Lidocaine hydrochloride and epinephrine  
injection, solution (Hospira, Inc.)  
Revision date: 27-Jul-2017

Page 10 of 11

Version: 1.0

**15. REGULATORY INFORMATION**

CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	Schedule 6
	231-595-7
<b>Lidocaine Hydrochloride</b>	
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
<b>Sodium chloride</b>	
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
<b>SODIUM HYDROXIDE</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
California Proposition 65	454 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	215-185-5
<b>Sodium metabisulfite USP</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	
	231-673-0
<b>Water for injection</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	
	231-791-2



## SAFETY DATA SHEET

Material Name: Lidocaine hydrochloride and epinephrine  
injection, solution (Hospira, Inc.)  
Revision date: 27-Jul-2017

Page 11 of 11

Version: 1.0

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

Acute toxicity, oral-Cat.3; H302 - Harmful if swallowed  
Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage  
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage  
Acute toxicity, dermal-Cat.2; H310 - Fatal in contact with skin  
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation  
Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed

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

**Reasons for Revision:** New data sheet.

**Revision date:** 27-Jul-2017

**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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

**End of Safety Data Sheet**





## SAFETY DATA SHEET

Revision date: 26-Jul-2017

Version: 1.1

Page 1 of 10

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

#### Product Identifier

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

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

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

**Intended Use:** Pharmaceutical product anesthetic agent

#### Details of the Supplier of the Safety Data Sheet

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

Hospira UK Limited

Horizon

Honey Lane

Hurley

Maidenhead, SL6 6RJ

United Kingdom

**Emergency telephone number:**

**CHEMTREC (24 hours):** 1-800-424-9300

**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**

**International CHEMTREC (24 hours):** +1-703-527-3887

### 2. HAZARDS IDENTIFICATION

#### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

#### Label Elements

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

#### Other Hazards

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

#### Note:

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

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### Hazardous

## SAFETY DATA SHEET

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

Page 2 of 10

Revision date: 26-Jul-2017

Version: 1.1

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

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

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

**Additional Information:**

\* Proprietary

\*\* to adjust pH

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

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

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:**

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

**Skin Contact:**

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

**Ingestion:**

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

**Inhalation:**

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

**Most Important Symptoms and Effects, Both Acute and Delayed**

**Symptoms and Effects of Exposure:**

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

**Medical Conditions**

None known

**Aggravated by Exposure:**

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:**

None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:**

Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:**

Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:**

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

## SAFETY DATA SHEET

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

Page 3 of 10

Revision date: 26-Jul-2017

Version: 1.1

#### 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<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

#### SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit: 2 mg/m<sup>3</sup>

Australia PEAK 2 mg/m<sup>3</sup>

Austria OEL - MAKs 2 mg/m<sup>3</sup>

Bulgaria OEL - TWA 2.0 mg/m<sup>3</sup>

Czech Republic OEL - TWA 1 mg/m<sup>3</sup>

Estonia OEL - TWA 1 mg/m<sup>3</sup>

France OEL - TWA 2 mg/m<sup>3</sup>

Greece OEL - TWA 2 mg/m<sup>3</sup>

Hungary OEL - TWA 2 mg/m<sup>3</sup>

Japan - OELs - Ceilings 2 mg/m<sup>3</sup>

Latvia OEL - TWA 0.5 mg/m<sup>3</sup>

OSHA - Final PELs - TWAs: 2 mg/m<sup>3</sup>

## SAFETY DATA SHEET

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

Page 4 of 10

Revision date: 26-Jul-2017

Version: 1.1

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

### HYDROCHLORIC ACID

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

## SAFETY DATA SHEET

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

Page 5 of 10

Revision date: 26-Jul-2017

Version: 1.1

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

### Lidocaine Hydrochloride

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

### Sodium chloride

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

### Exposure Controls

<b>Engineering Controls:</b>	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.
<b>Personal Protective Equipment:</b>	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.
<b>Hands:</b>	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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Solution	<b>Color:</b>	Clear, colorless
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	5-7		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Lidocaine Hydrochloride</b>			
No data available			

## SAFETY DATA SHEET

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

Page 6 of 10

Revision date: 26-Jul-2017

Version: 1.1

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Water for injection

No data available

### Sodium chloride

No data available

### HYDROCHLORIC ACID

No data available

### SODIUM HYDROXIDE

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

### Flammability:

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

**Flammability (Solids):** No data available

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

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

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

## 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions of use.

### Possibility of Hazardous Reactions

**Oxidizing Properties:** No data available

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

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

**Hazardous Decomposition Products:** No data available

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

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

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

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

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

Lidocaine Hydrochloride



## SAFETY DATA SHEET

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

**Page 7 of 10**

**Revision date:** 26-Jul-2017

**Version:** 1.1

### 11. TOXICOLOGICAL INFORMATION

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

#### Sodium chloride

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

#### HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

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

##### Lidocaine Hydrochloride

Eye Irritation Rabbit Mild  
 Skin Irritation Rabbit Mild

##### Sodium chloride

Eye Irritation Rabbit Moderate  
 Skin Irritation Rabbit Mild

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

##### Lidocaine Hydrochloride

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

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

##### Lidocaine Hydrochloride

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

##### HYDROCHLORIC ACID

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

#### Carcinogen Status:

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

#### HYDROCHLORIC ACID

**IARC:** Group 3 (Not Classifiable)

## SAFETY DATA SHEET

Material Name: Lidocaine Hydrochloride Injection (Hospira, Inc.)  
 Revision date: 26-Jul-2017

Page 8 of 10

Version: 1.1

**12. ECOLOGICAL INFORMATION**

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

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

**13. DISPOSAL CONSIDERATIONS**

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

**14. TRANSPORT INFORMATION**

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

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

**15. REGULATORY INFORMATION**

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

Lidocaine Hydrochloride

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

200-803-8

Sodium chloride

## SAFETY DATA SHEET

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

Page 9 of 10

Revision date: 26-Jul-2017

Version: 1.1

### 15. REGULATORY INFORMATION

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

#### Water for injection

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

#### SODIUM HYDROXIDE

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

#### HYDROCHLORIC ACID

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

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

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

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

#### Data Sources:

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

**SAFETY DATA SHEET**

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

**Page 10 of 10**

**Revision date:** 26-Jul-2017

**Version:** 1.1

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

**Revision date:** 26-Jul-2017

**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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

**End of Safety Data Sheet**



## SAFETY DATA SHEET

### Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

#### 1. IDENTIFICATION

<b>Product Identifier:</b>	Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%
<b>Synonyms:</b>	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate
<b>National Drug Code (NDC):</b>	50383-775-04 50383-775-17
<b>Recommended Use:</b>	Pharmaceutical. Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2% is indicated for the production of topical anesthesia of irritated or inflamed mucous membranes of the mouth and pharynx. It is also useful for reducing gagging during the taking of X-ray pictures and dental impressions.
<b>Company:</b>	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
<b>Contact Telephone:</b>	1-800-932-5676
<b>E mail:</b>	customer.service@akorn.com
<b>Emergency Phone Number:</b>	CHEMTREC 1-800-424-9300 (U.S. and Canada)

#### 2. HAZARD(S) IDENTIFICATION

<b>Physical Hazards:</b>	Not classified.	
<b>Health Hazards:</b>	Specific Target Organ Toxicity – Repeated Exposure	Category 2
<b>Symbol(s):</b>		
<b>Signal Word:</b>	Warning.	
<b>Hazard Statement(s):</b>	H373 May cause damage to organs through prolonged or repeated exposure.	
<b>Precautionary Statement(s):</b>	P260 Do not breathe vapor or spray. P264 Wash hands thoroughly after handling. P314 Get medical attention if you feel unwell.	



## SAFETY DATA SHEET

### Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

P305 IF IN EYES: Rinse cautiously with water for  
+ several minutes. Remove contact lenses, if  
P351 present and easy to do. Continue rinsing.  
+  
P338

P337 If eye irritation persists: Get medical attention.  
+  
P313

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

**Hazards Not Otherwise Classified:** Not classifiable.

**Supplementary Information:** None.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Lidocaine Hydrochloride	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate	6108-05-0	C <sub>14</sub> H <sub>22</sub> N <sub>2</sub> O	234.34	2%

The formula also contains the following inactive ingredients: Carboxymethylcellulose Sodium, Methylparaben, Natural Orange Flavor, Propylparaben, Purified Water, and Saccharin Sodium. The pH is adjusted to 5.0 to 7.0 by means of Hydrochloric Acid and/or Sodium Hydroxide.

### 4. FIRST AID MEASURES

**Ingestion:**

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

**Eye Contact:**

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



## SAFETY DATA SHEET

### Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

**Skin Contact:**

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Inhalation:**

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Protection of First-Aiders:**

Use personal protective equipment (see section 8).

**Signs and Symptoms:**

Inadvertent contact with this product may cause irritation, followed by numbness. Ingestion may cause numbness of the tongue and anesthetic effects on the stomach. In clinical use, this product produces numbness when injected. Systemic absorption can produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Allergic-type reactions are rare but may occur due to sensitivity to the local anesthetic or to other formulation ingredients. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal edema), tachycardia, sneezing, nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other amide-type local anesthetics has been reported.

**Medical Conditions Aggravated  
by Exposure:**

As with all pharmaceuticals, hypersensitivity is possible.

**Notes to Physician:**

Treat supportively and symptomatically. Excessive dosage, or short intervals between doses, can result in high plasma levels and serious adverse effects. Patients should be instructed to strictly adhere to the recommended dosage and administration guidelines as set forth in the package insert. The management of serious adverse reactions may require the use of



## SAFETY DATA SHEET

### Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

resuscitative equipment, oxygen and other resuscitative drugs.

#### 5. FIREFIGHTING MEASURES

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

**Unsuitable Extinguishing Media:** Not determined.

#### Specific Hazards Arising from the Chemical

**Hazardous Combustion Products:** None.

**Other Specific Hazards:** Closed containers may explode from the heat of fire.

**Special Protective Equipment and Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions:** Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

**Personal Protective Equipment:** For personal protection see section 8.

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

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

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

#### 7. HANDLING AND STORAGE

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

**Conditions for Safe Storage, Including Any Incompatibilities:** Store at 15° to 30°C (59° to 86°F) Shake well before use. Store according to label and/or product insert information.

**Specific End Use:** Pharmaceutical drug product.





## SAFETY DATA SHEET

### Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

#### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

##### Occupational Exposure Guidelines:

Ingredient	Type	Value
Lidocaine Hydrochloride	Not established	Not established

##### Engineering Controls:

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

##### Respiratory Protection:

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

##### Eyes Protection:

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

##### Hand Protection:

Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

##### Skin Protection:

Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

##### General Hygiene Considerations:

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



## SAFETY DATA SHEET

### Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State/Color:</b>	Clear, viscous solution.
<b>Odor:</b>	No data available.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	5.0 to 7.0.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	>150°F.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	>1.
<b>Relative Density:</b>	Approximately that of water.
<b>Solubility(ies):</b>	Very soluble in water and alcohol; soluble in chloroform; insoluble in ether.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

#### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	No data available.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Contact with incompatible materials.
<b>Incompatible Materials:</b>	Strongly alkaline conditions. Methyl vinyl ether; zinc.
<b>Hazardous Decomposition Products:</b>	During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.



## SAFETY DATA SHEET

### Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

#### 11. TOXICOLOGICAL INFORMATION

##### Information on the Likely Routes of Exposure

**Inhalation:** No data available.

**Ingestion:** Harmful if swallowed.

**Skin Contact:** No data available.

**Eye Contact:** No data available.

##### **Symptoms Related to the Physical, Chemical and Toxicological Characteristics:**

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

##### **Delayed and Immediate Effects of Exposure:**

No data available.

##### Acute Toxicity

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

Ingredient	Species	Route	Test Type	Dosage
Lidocaine Hydrochloride	Mouse	Oral	LD <sub>50</sub>	292 mg/kg
Lidocaine Hydrochloride	Rat	Oral	LD <sub>50</sub>	159-324 mg/kg

##### Irritation / Sensitization

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

##### Repeated Dose Toxicity

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

##### Reproduction and Developmental Toxicity

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



## SAFETY DATA SHEET

### Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

#### Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
Lidocaine Hydrochloride	Ames Test	S. typhimurium and E. coli	Negative
Lidocaine Hydrochloride	Chromosomal aberration assay	Human lymphocytes	Negative
Lidocaine Hydrochloride	<i>In Vivo</i> micronucleus assay	Mouse	Negative

<b>Aspiration Hazard:</b>	None anticipated from normal handling of this product.
<b>Toxicokinetics/Metabolism:</b>	See package insert for more information.
<b>Target Organ Effects:</b>	Based on clinical use, possible target organs include the nervous system and cardiovascular system.
<b>Reproductive Effects:</b>	Pregnancy Category B. Reproduction studies have been performed in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine.
<b>Carcinogenicity:</b>	Studies of lidocaine in animals to evaluate the carcinogenic potential have not been conducted.
<b>National Toxicology Program (NTP):</b>	Not considered to be a carcinogen.
<b>International Agency for Research on Cancer (IARC):</b>	Not considered to be a carcinogen.
<b>Occupational Safety and Health Administration (OSHA):</b>	Not considered to be a carcinogen.

## 12. ECOLOGICAL INFORMATION

#### Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Lidocaine Hydrochloride	Daphnia magna	EC <sub>50</sub>	112 mg/l	48 hours
Lidocaine Hydrochloride	Zebra danio (Danio rerio)	LC <sub>50</sub>	106 mg/l	96 hours

<b>Terrestrial Toxicity:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	No data available.
<b>Other Adverse Effects:</b>	No data available.



## SAFETY DATA SHEET

### Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

#### 13. DISPOSAL CONSIDERATIONS

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

#### 14. TRANSPORT INFORMATION

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

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

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

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

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

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

#### 15. REGULATORY INFORMATION

##### US FEDERAL REGULATIONS

**Toxic Substance Control Act (TSCA):**

Ingredient	Inventory
Lidocaine Hydrochloride	No

**CERCLA Hazardous Substance:**

Ingredient	Reportable Quantity
Not applicable	Not applicable

**EPCRA Extremely Hazardous Substances and Toxic Chemicals:**

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable



## SAFETY DATA SHEET

### Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

#### U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Lidocaine Hydrochloride	Listed	Listed	Not Listed

**California Proposition 65:**

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

#### 16. OTHER INFORMATION

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

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

**SAFETY DATA SHEET****M-M-R II Vaccine**

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

**SECTION 1. IDENTIFICATION**

Product name : M-M-R II Vaccine

**Manufacturer or supplier's details**

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road  
Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with 29 CFR 1910.1200**

|| Combustible dust

**GHS label elements**

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

**Other hazards**

|| Dust contact with the eyes can lead to mechanical irritation.  
|| Contact with dust can cause mechanical irritation or drying of the skin.

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

Substance / Mixture : Mixture

**Hazardous ingredients**

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	$\geq 1$ - $< 5$
Neomycin, sulfate (salt)	1405-10-3	$< 0.1$

**SECTION 4. FIRST AID MEASURES**

**SAFETY DATA SHEET****M-M-R II Vaccine**

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

- |   |   |  |
|---|---|--|
| General advice  | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled  | : | If inhaled, remove to fresh air.<br>Get medical attention if symptoms occur.   |
| In case of skin contact                                     | : | Wash with water and soap.<br>Get medical attention if symptoms occur.  |
| In case of eye contact                                      | : | If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.   |
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>Rinse mouth thoroughly with water.                                |
| Most important symptoms and effects, both acute and delayed | : | Contact with dust can cause mechanical irritation or drying of the skin.<br>Dust contact with the eyes can lead to mechanical irritation.              |
| Protection of first-aiders                                  | : | No special precautions are necessary for first aid responders.   |
| Notes to physician  | : | Treat symptomatically and supportively.  |

**SECTION 5. FIRE-FIGHTING MEASURES**

- |                                       |   |   |
|---------------------------------------|---|---|
| Suitable extinguishing media          | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical  |
| Unsuitable extinguishing media        | : | None known.   |
| Specific hazards during fire fighting | : | Exposure to combustion products may be a hazard to health.  |
| Hazardous combustion products         | : | Carbon oxides<br>Metal oxides<br>Chlorine compounds<br>Oxides of phosphorus<br>Phosphorus compounds<br>Nitrogen oxides (NO <sub>x</sub> )   |
| Specific extinguishing methods        | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment          | : | Wear self-contained breathing apparatus for firefighting if nec-  |



**SAFETY DATA SHEET****M-M-R II Vaccine**

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

for fire-fighters

essary.

Use personal protective equipment.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures : Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions : Discharge into the environment must be avoided.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

**SECTION 7. HANDLING AND STORAGE**

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.  
Handle in accordance with good industrial hygiene and safety practice.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.  
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

## SAFETY DATA SHEET



## M-M-R II Vaccine

Version 4.0      Revision Date: 04/13/2017      SDS Number: 81085-00006      Date of last issue: 10/28/2016  
Date of first issue: 03/26/2015

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m <sup>3</sup> (OEB 1)	Merck
	Further information: DSEN			
		Wipe limit	0.1 mg/100 cm <sup>2</sup>	Merck

**Engineering measures** : Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m<sup>3</sup> - total dust, 5 mg/m<sup>3</sup> - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m<sup>3</sup> - respirable particles, 10 mg/m<sup>3</sup> - inhalable particles.

**Personal protective equipment**

**Respiratory protection** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

## SAFETY DATA SHEET



## M-M-R II Vaccine

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

Material	:	Chemical-resistant gloves
Remarks	:	For prolonged or repeated contact use protective gloves. Wash hands before breaks and at the end of workday.
Eye protection	:	Wear the following personal protective equipment: Safety goggles
Skin and body protection	:	Skin should be washed after contact.
Hygiene measures	:	Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	No data available
Odor	:	No information available.
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	No data available

## SAFETY DATA SHEET



## M-M-R II Vaccine

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

## SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Dust can form an explosive mixture in air. Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

## SECTION 11. TOXICOLOGICAL INFORMATION

## Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

## Acute toxicity

Not classified based on available information.

**Product:**

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
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## SAFETY DATA SHEET



## M-M-R II Vaccine

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

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**Ingredients:****Sucrose:**

Acute oral toxicity	:	LD50 (Rat): 29,700 mg/kg
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**Neomycin, sulfate (salt):**

Acute oral toxicity	:	LD50 (Mouse): 2,880 mg/kg
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		LD50 (Rat): 2,750 mg/kg
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Acute toxicity (other routes of administration)	:	LD50 (Rat): 633 mg/kg Application Route: Subcutaneous
---	---	--

		LD50 (Mouse): 116 mg/kg Application Route: Intraperitoneal
--	--	---

		LD50 (Mouse): 27.6 mg/kg Application Route: Intravenous
--	--	--

		LD50 (Mouse): 275 mg/kg Application Route: Subcutaneous
--	--	--

**Skin corrosion/irritation**

Not classified based on available information.

**Ingredients:****Neomycin, sulfate (salt):**

Species: Rabbit
-----------------

Result: Mild skin irritation
------------------------------

**Serious eye damage/eye irritation**

Not classified based on available information.

**Ingredients:****Neomycin, sulfate (salt):**

Species: Rabbit
-----------------

Result: No eye irritation
---------------------------

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Ingredients:****Neomycin, sulfate (salt):**

Routes of exposure: Dermal
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Species: Humans
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Result: positive
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## SAFETY DATA SHEET



## M-M-R II Vaccine

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

## II

**Germ cell mutagenicity**

Not classified based on available information.

**Ingredients:****Sucrose:**

Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test Result: negative
-----------------------	---	---

**Neomycin, sulfate (salt):**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	:	Test Type: In vitro mammalian cell gene mutation test Species: Chinese hamster ovary cells Result: negative
	:	Test Type: Chromosomal aberration Species: Human lymphocytes Result: positive
	:	Test Type: in vitro micronucleus test Result: negative
Genotoxicity in vivo	:	Test Type: Cytogenetic assay Species: Mouse Cell type: Bone marrow Application Route: Intravenous injection Result: negative

**Carcinogenicity**

Not classified based on available information.

**Ingredients:****Neomycin, sulfate (salt):**

Species: Rat
Exposure time: 2 Years
Result: negative

**IARC**

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

**OSHA**

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP**

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

## SAFETY DATA SHEET



## M-M-R II Vaccine

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

**Reproductive toxicity**

Not classified based on available information.

**Ingredients:****Neomycin, sulfate (salt):**

Effects on fertility	:	Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity Parent: NOAEL: 25 mg/kg body weight Result: No effects on fertility and early embryonic development were detected.
Effects on fetal development	:	Test Type: Embryo-fetal development Application Route: Oral Embryo-fetal toxicity.: NOAEL: 275 mg/kg body weight Result: No adverse effects., No teratogenic effects.
		Test Type: Development Application Route: Subcutaneous Developmental Toxicity: LOAEL: 6 mg/kg body weight Result: positive
Reproductive toxicity - Assessment	:	Some evidence of adverse effects on development, based on animal experiments.

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Ingredients:****Neomycin, sulfate (salt):**

Target Organs: Kidney, inner ear  
Assessment: May cause damage to organs through prolonged or repeated exposure.  
Remarks: Based on human experience.

**Repeated dose toxicity****Ingredients:****Neomycin, sulfate (salt):**

Species: Mouse  
LOAEL: 30 mg/kg  
Application Route: Subcutaneous  
Exposure time: 14 d  
Target Organs: Kidney

Species: Guinea pig  
NOAEL: 50 mg/kg  
LOAEL: 100 mg/kg  
Application Route: Intramuscular  
Exposure time: 30 - 60 Weeks

## SAFETY DATA SHEET



## M-M-R II Vaccine

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

Target Organs: ear

Species: Guinea pig

NOAEL: 10 mg/kg

Application Route: Oral

Exposure time: 90 d

Remarks: No significant adverse effects were reported

Species: Guinea pig

LOAEL: 100 mg/kg

Application Route: Subcutaneous

Exposure time: 34 d

Species: Dog

NOAEL: 100 mg/kg

Application Route: Oral

Exposure time: 6 Weeks

Remarks: No significant adverse effects were reported

Species: Dog

LOAEL: 24 mg/kg

Application Route: Intramuscular

Exposure time: 30 d

Target Organs: Kidney

Species: Rat

LOAEL: 25 mg/kg

Application Route: oral (feed)

Exposure time: 84 Weeks

Target Organs: ear

Symptoms: hearing loss

Remarks: mortality observed

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Ingredients:****Neomycin, sulfate (salt):**

Skin contact

: Symptoms: Sensitization  
Remarks: May irritate skin.

Eye contact

: Remarks: May cause eye irritation.

Ingestion

: Symptoms: Nausea, Vomiting, Diarrhea, tinnitus, hearing loss,  
Loss of balance



## SAFETY DATA SHEET



## M-M-R II Vaccine

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

## SECTION 12. ECOLOGICAL INFORMATION

## Ecotoxicity

Ingredients:

## Neomycin, sulfate (salt):

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 72 mg/l
		Exposure time: 48 h
		Method: OECD Test Guideline 202
		LC50 (Americamysis): 39 mg/l
		Exposure time: 96 h
		Method: US-EPA OPPTS 850.1035
Toxicity to algae	:	EC50 (Anabaena flos-aquae (cyanobacterium)): 0.00075 mg/l
		Exposure time: 72 h
		Method: OECD Test Guideline 201
		NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0003 mg/l
		Exposure time: 72 h
		Method: OECD Test Guideline 201
		EC50 (Pseudokirchneriella subcapitata (green algae)): 0.0099 mg/l
		Exposure time: 72 h
		Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0022 mg/l
		Exposure time: 72 h
		Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1,000
M-Factor (Chronic aquatic toxicity)	:	10
Toxicity to microorganisms	:	EC50 (Natural microorganism): 107.6 mg/l
		Exposure time: 3 h
		Test Type: Respiration inhibition
		Method: OECD Test Guideline 209
		EC10 (Natural microorganism): 2.8 mg/l
		Exposure time: 3 h
		Test Type: Respiration inhibition
		Method: OECD Test Guideline 209

## Persistence and degradability

Ingredients:

## Neomycin, sulfate (salt):

## SAFETY DATA SHEET



## M-M-R II Vaccine

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

Biodegradability : Result: rapidly degradable  
 Biodegradation: 50 %  
 Exposure time: 1.2 d  
 Method: OECD Test Guideline 314

**Bioaccumulative potential****Ingredients:****Sucrose:**

Partition coefficient: n-octanol/water : Pow: < 1

**Neomycin, sulfate (salt):**

Partition coefficient: n-octanol/water : log Pow: < -2

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
 If not otherwise specified: Dispose of as unused product.

**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : UN 3077  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
 (Neomycin, sulfate (salt))  
 Class : 9  
 Packing group : III  
 Labels : 9

**IATA-DGR**

UN/ID No. : UN 3077  
 Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
 (Neomycin, sulfate (salt))  
 Class : 9  
 Packing group : III  
 Labels : Miscellaneous

## SAFETY DATA SHEET



## M-M-R II Vaccine

Version 4.0      Revision Date: 04/13/2017      SDS Number: 81085-00006      Date of last issue: 10/28/2016  
Date of first issue: 03/26/2015

Packing instruction (cargo aircraft) : 956

Packing instruction (passenger aircraft) : 956

**IMDG-Code**

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Neomycin, sulfate (salt))

Class : 9

Packing group : III

Labels : 9

EmS Code : F-A, S-F

Marine pollutant : yes

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

Not applicable for product as supplied.

**Domestic regulation****49 CFR**

UN/ID/NA number : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Neomycin, sulfate (salt))

Class : 9

Packing group : III

Labels : CLASS 9

ERG Code : 171

Marine pollutant : yes (Neomycin, sulfate (salt))

Remarks : Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

**SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

Ingredients	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Disodium hydrogenorthophosphate	7558-79-4	5000	90909

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Fire Hazard

## SAFETY DATA SHEET



## M-M-R II Vaccine

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

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

## US State Regulations

## Pennsylvania Right To Know

D-Glucitol	50-70-4
Gelatins	9000-70-8
Sodium chloride	7647-14-5
Sodium phosphate, monobasic	7558-80-7
Disodium hydrogenorthophosphate	7558-79-4
Sucrose	57-50-1

## California Prop. 65

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

Neomycin, sulfate (salt)	1405-10-3
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## California List of Hazardous Substances

Disodium hydrogenorthophosphate	7558-79-4
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## California Permissible Exposure Limits for Chemical Contaminants

Sucrose	57-50-1
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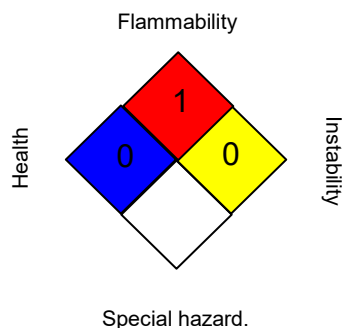
## The ingredients of this product are reported in the following inventories:

AICS	: not determined
DSL	: not determined
IECSC	: not determined

## SECTION 16. OTHER INFORMATION

## Further information

## NFPA:



## HMIS® IV:

HEALTH	/	0
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

## SAFETY DATA SHEET



## M-M-R II Vaccine

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

**Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a>
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Revision Date	:	04/13/2017
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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a

**SAFETY DATA SHEET****M-M-R II Vaccine**

Version	Revision Date:	SDS Number:	Date of last issue: 10/28/2016
4.0	04/13/2017	81085-00006	Date of first issue: 03/26/2015

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guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

US / Z8



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;



SDS DATE: 10/29/15

**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.

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**SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS**


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<b>INGREDIENT</b>	<b>CAS NO.</b>	<b>%</b>	<b>Exposure Limits</b>
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**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]





SDS DATE: 10/29/15

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.

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#### SECTION 4: FIRST-AID MEASURES

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**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**

<b>Overview</b>	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.
<b>Eyes</b>	Causes serious eye damage.
<b>Skin</b>	Causes severe skin burns and eye damage.

---

#### SECTION 5: FIRE-FIGHTING MEASURES

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**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**

<b>HEALTH:</b>	N/A	<b>FLAMMABILITY:</b>	N/A	<b>REACTIVITY:</b>	N/A	<b>OTHER:</b>	N/A
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**HMIS HAZARD CLASSIFICATION**

<b>HEALTH:</b>	N/A	<b>FLAMMABILITY:</b>	N/A	<b>REACTIVITY:</b>	N/A	<b>PERSONAL:</b>	N/A
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**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.

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#### SECTION 6: ACCIDENTAL RELEASE MEASURES

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**ACCIDENTAL RELEASE MEASURES:** N/A

**SECTION 6 NOTES:**

**Personal precautions, protective equipment and emergency procedures**

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



SDS DATE: 10/29/15

**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.

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**SECTION 7: HANDLING AND STORAGE**


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

**STORAGE:** Handle containers carefully to prevent damage and spillage.

Incompatible materials: Reducing agents, combustible materials.

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

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

**OTHER PRECAUTIONS:** N/A

**SECTION 7 NOTES:** N/A

---

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**


---

**ENGINEERING CONTROLS:** N/A

**VENTILATION:**

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

**EYE PROTECTION:** Protective goggles if desired.

**SKIN PROTECTION:** Rubber or vinyl gloves.

**OTHER PROTECTIVE CLOTHING OR EQUIPMENT:** N/A

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

**EXPOSURE GUIDELINES:**

**SECTION 8 NOTES:** N/A

---

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**


---

**APPEARANCE & ODOR:** Clear, colorless, odorless liquid

**PHYSICAL STATE:** N/A

**pH AS SUPPLIED:** N/A

**pH (Other):** N/A

**BOILING POINT:** 212°F

**MELTING POINT:** N/A

**FREEZING POINT:** N/A

**VAPOR PRESSURE (mmHg):** 23

@ N/A

**DENSITY (lb/gal):** N/A

@ N/A

**SPECIFIC GRAVITY (H<sub>2</sub>O = 1):** 1.1



SDS DATE: 10/29/15

@ 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%

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**SECTION 10: STABILITY AND REACTIVITY**


---

**STABLE****UNSTABLE****STABILITY:** Stable under normal conditions.**CONDITIONS TO AVOID (STABILITY):** Extreme heat and combustion.**INCOMPATIBILITY (MATERIAL TO AVOID):** Reducing agents, combustible materials.**HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:** Oxygen, which supports combustion.**HAZARDOUS POLYMERIZATION:** Will not occur.**CONDITIONS TO AVOID (POLYMERIZATION):** N/A**SECTION 10 NOTES:** N/A

---

**SECTION 11: TOXICOLOGICAL INFORMATION**


---

**TOXICOLOGICAL INFORMATION:**

## Acute Toxicity

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

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



SDS DATE: 10/29/15

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

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**SECTION 12: ECOLOGICAL INFORMATION**


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**ECOLOGICAL INFORMATION:**

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

**Aquatic Ecotoxicity**

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

**Persistence and degradability**

There is no data available on the preparation itself.

**Bioaccumulative potential**

Not Measured

**Mobility in soil**

No data available.

**Results of PBT and vPvB assessment**

This product contains no PBT/vPvB chemicals.

**Other adverse effects**

No data available.

SECTION 12 NOTES: N/A

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**SECTION 13: DISPOSAL CONSIDERATIONS**


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



SDS DATE: 10/29/15

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

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**SECTION 14: TRANSPORT INFORMATION**


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**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

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**SECTION 15: REGULATORY INFORMATION**


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**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%):**



**SDS DATE: 10/29/15**

No chemicals at levels which require reporting under this statute.

**INTERNATIONAL REGULATIONS:** N/A

**SECTION 15 NOTES:** N/A

---

**SECTION 16: OTHER INFORMATION**

---

**OTHER INFORMATION:** N/A

**PREPARATION INFORMATION:** N/A

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



SDS DATE: 9/18/2015

## \*SAFETY DATA SHEET\*

## SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: McKesson Premium Instant Hand Sanitizer  
MFR #: 53-28032-4, 53-28033-8, 53-28035-1000, 53-28037-18

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

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

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

PRODUCT DESCRIPTION: A gelled alcohol hand sanitizer for hand washing to decrease bacteria on the skin

## 2. HAZARDS IDENTIFICATION

**Classification**

Flammable Liquids

Category 2

**Signal Word**

Danger

**Hazard Statements**

Highly flammable liquid and vapor

**Appearance:** Clear blue gel**Physical State** Gel**Odor** Alcohol**Precautionary Statements - Prevention**

Keep away from heat/sparks/open flames/hot surfaces. — No smoking  
Keep container tightly closed  
Ground/bond container and receiving equipment  
Use explosion-proof equipment  
Use only non-sparking tools  
Take precautionary measures against static discharge  
Wear protective gloves/protective clothing/eye protection/face protection

**Precautionary Statements - Response**

IN CASE OF FIRE: Use CO<sub>2</sub>, dry chemical, or foam for extinction

**Precautionary Statements - Storage**

Store in a well-ventilated place

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Other Hazards**

Toxic to aquatic life with long lasting effects



SDS DATE: 9/18/2015

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%
Ethanol	64-17-5	70

### 4. FIRST-AID MEASURES

#### First Aid Measures

<b>Eye Contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
<b>Skin Contact</b>	If skin irritation occurs, rinse affected area with water.
<b>Inhalation</b>	Remove to fresh air.
<b>Ingestion</b>	Dilute by giving a large amount of water. Call a physician or Poison Control Center.

#### Most important symptoms and effects

<b>Symptoms</b>	Exposed individuals may experience eye tearing, redness and discomfort. May cause gastrointestinal disturbance. Inhalation may cause giddiness or loss of consciousness.
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#### Indication of any immediate medical attention and special treatment needed

<b>Notes to Physician</b>	Treat symptomatically.
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### 5. FIRE-FIGHTING MEASURES

#### Suitable Extinguishing Media

Carbon dioxide (CO<sub>2</sub>). Alcohol resistant foam. Dry chemical.

**Unsuitable Extinguishing Media** Not determined.

#### Specific Hazards Arising from the Chemical

Vapors may travel to source of ignition and flash back. Alcohol flames may be difficult to see; the flames are virtually colorless.

**Hazardous Combustion Products** Carbon oxides.

#### Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Use cool water to cool equipment and to disperse vapors.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal precautions, protective equipment and emergency procedures

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

#### Methods and material for containment and cleaning up

<b>Methods for Containment</b>	Prevent further leakage or spillage if safe to do so.
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**SDS DATE: 9/18/2015**
**Methods for Clean-Up**

Small spills (less than 1 gallon) may be washed down a drain with lots of water or cleaned up and disposed of into a sanitary sewer system.  
Large spills (more than 1 gallon) should be contained and collected (by absorption [sand, clay, or other absorbent material] or vacuuming) then disposed of properly.

**7. HANDLING AND STORAGE**
**Precautions for safe handling**
**Advice on Safe Handling**

Keep away from heat/sparks/open flames/hot surfaces. — No smoking. Use spark-proof tools and explosion-proof equipment. Ground/bond container and receiving equipment. Take precautionary measures against static discharges.

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

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

**Incompatible Materials**

Strong oxidizers. Hydrogen peroxide. Bromine. Chromic acid.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**
**Exposure Guidelines**

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Ethanol 64-17-5	STEL: 1000 ppm	TWA: 1000 ppm TWA: 1900 mg/m <sup>3</sup> (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m <sup>3</sup>	IDLH: 3300 ppm TWA: 1000 ppm TWA: 1900 mg/m <sup>3</sup>



SDS DATE: 9/18/2015

Glycerol 56-81-5	TWA: 10 mg/m <sup>3</sup> mist	TWA: 15 mg/m <sup>3</sup> mist, total particulate TWA: 5 mg/m <sup>3</sup> mist, respirable fraction (vacated) TWA: 10 mg/m <sup>3</sup> mist, total particulate (vacated) TWA: 5 mg/m <sup>3</sup> mist, respirable fraction	-
Isopropyl alcohol 67-63-0	STEL: 400 ppm TWA: 200 ppm	TWA: 400 ppm TWA: 980 mg/m <sup>3</sup> (vacated) TWA: 400 ppm (vacated) TWA: 980 mg/m <sup>3</sup> (vacated) STEL: 500 ppm (vacated) STEL: 1225 mg/m <sup>3</sup>	IDLH: 2000 ppm TWA: 400 ppm TWA: 980 mg/m <sup>3</sup> STEL: 500 ppm STEL: 1225 mg/m <sup>3</sup>

**Appropriate engineering controls**

**Engineering Controls** Apply technical measures to comply with the occupational exposure limits. Ventilation systems.

**Individual protection measures, such as personal protective equipment**

**Eye/Face Protection** Avoid contact with eyes.

**Skin and Body Protection** No special technical protective measures are necessary.

**Respiratory Protection** No protective equipment is needed under normal use conditions.

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

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>
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**Information on basic physical and chemical properties**

<b>Physical State</b>	Gel	<b>Odor</b>	Alcohol
<b>Appearance</b>	Clear blue gel	<b>Odor Threshold</b>	Not determined
<b>Color</b>	blue		
<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks • Method</u></b>	
pH	6.00-8.00		
Melting Point/Freezing Point	Not established		
Boiling Point/Boiling Range	100 °C / 212 °F		
Flash Point	21 °C / 70 °F	SETA	
Evaporation Rate	Not established		
Flammability (Solid, Gas)	Not determined		
Upper Flammability Limits	Not determined		
Lower Flammability Limit	Not determined		
Vapor Pressure	Not established		
Vapor Density	Not established		
Specific Gravity	.858 - .882		
Water Solubility	Completely soluble		
Solubility in other solvents	Not determined		
<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks • Method</u></b>	
Partition Coefficient	Not determined		
Autoignition Temperature	Not determined		
Decomposition Temperature	Not determined		
Kinematic Viscosity	Not determined		
Dynamic Viscosity	6000-10000 cps		
Explosive Properties	Not determined		



SDS DATE: 9/18/2015

**Oxidizing Properties**  
**Density**

Not determined  
7.15-7.35 lb/gal

## 10. STABILITY AND REACTIVITY

### Reactivity

Not reactive under normal conditions.

### Chemical Stability

Stable under recommended storage conditions.

### Possibility of Hazardous Reactions

None under normal processing.

### **Hazardous Polymerization**

Hazardous polymerization does not occur.

### Conditions to Avoid

Keep out of reach of children.

### Incompatible Materials

Strong oxidizers. Hydrogen peroxide. Bromine. Chromic acid.

### Hazardous Decomposition Products

Carbon oxides.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

#### **Product Information**

#### **Eye Contact**

Avoid contact with eyes.

#### **Skin Contact**

Not expected to be a skin irritant during prescribed use.

#### **Inhalation**

Avoid breathing vapors or mists.

#### **Ingestion**

Do not taste or swallow.

### Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Ethanol 64-17-5	= 7060 mg/kg ( Rat )	-	= 124.7 mg/L ( Rat ) 4 h
Carbomer 9003-01-4	= 2500 mg/kg ( Rat )	-	-
Glycerol 56-81-5	= 12600 mg/kg ( Rat )	> 21900 mg/kg ( Rat )	-
Isopropyl alcohol 67-63-0	= 4396 mg/kg ( Rat )	= 12800 mg/kg ( Rat ) = 12870 mg/kg ( Rabbit )	= 72.6 mg/L ( Rat ) 4 h
Isopropyl Myristate 110-27-0	> 10000 mg/kg ( Rat )	= 5 g/kg ( Rabbit )	> 41 mg/L ( Rat )
Propylene Glycol 25322-69-4	> 2 g/kg ( Rat )	-	-

### Information on physical, chemical and toxicological effects

#### **Symptoms**

Please see section 4 of this SDS for symptoms.



SDS DATE: 9/18/2015

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

Isopropyl Alcohol (IPA) is listed as an IARC Monograph Group 3 chemical. However, IARC Group 3 chemicals are "not classifiable as human carcinogens". IPA is classified as an IARC Group 1 chemical ONLY when manufactured by the strong-acid process. The IPA used in this product is NOT manufactured by the strong-acid process and is therefore not classifiable as a human carcinogen. Ethanol has been shown to be carcinogenic in long-term studies only when consumed as an alcoholic beverage.

Chemical Name	ACGIH	IARC	NTP	OSHA
Ethanol 64-17-5	A3	Group 1	Known	X

**Legend**

**ACGIH (American Conference of Governmental Industrial Hygienists)**

A3 - Animal Carcinogen

**IARC (International Agency for Research on Cancer)**

Group 1 - Carcinogenic to Humans

Group 3 IARC components are "not classifiable as human carcinogens"

**NTP (National Toxicology Program)**

Known - Known Carcinogen

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

X - Present

**Numerical measures of toxicity**

Not determined

**12. ECOLOGICAL INFORMATION****Ecotoxicity**

Toxic to aquatic life with long lasting effects.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Ethanol 64-17-5		12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static 100: 96 h Pimephales promelas mg/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through		9268 - 14221: 48 h Daphnia magna mg/L LC50 10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static
Carbomer 9003-01-4		580: 96 h Lepomis macrochirus mg/L LC50		168: 96 h water flea mg/L EC50
Glycerol 56-81-5		51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static		500: 24 h Daphnia magna mg/L EC50
Isopropyl alcohol 67-63-0	1000: 96 h Desmodesmus subspicatus mg/L EC50 1000: 72 h Desmodesmus subspicatus mg/L EC50	9640: 96 h Pimephales promelas mg/L LC50 flow- through 11130: 96 h Pimephales promelas mg/L LC50 static 1400000: 96 h Lepomis macrochirus µg/L LC50		13299: 48 h Daphnia magna mg/L EC50
Isopropyl Myristate 110-27-0	100: 72 h Desmodesmus subspicatus mg/L EC50	8400: 96 h Brachydanio rerio mg/L LC50 semi-static 8400: 96 h Brachydanio rerio mg/L LC50		100: 48 h Daphnia magna mg/L EC50

**Persistence/Degradability**

Not determined

**Bioaccumulation**

Not determined

**Mobility**

Chemical Name	Partition Coefficient
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SDS DATE: 9/18/2015

Ethanol 64-17-5	-0.32
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**Other Adverse Effects**

Not determined

**13. DISPOSAL CONSIDERATIONS****Waste Treatment Methods**

<b>Disposal of Wastes</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations.
<b>Contaminated Packaging</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations.

**California Hazardous Waste Status**

Chemical Name	California Hazardous Waste Status
Ethanol 64-17-5	Toxic Ignitable

**14. TRANSPORT INFORMATION**

**Note** This product as packaged in 4oz, 8oz, 18oz & 1000mL is shipped as Limited Quantity

**DOT**

<b>UN/ID No</b>	UN1170
<b>Proper Shipping Name</b>	Ethanol solution
<b>Hazard Class</b>	3
<b>Packing Group</b>	II

**IATA**

<b>UN/ID No</b>	UN1170
<b>Proper Shipping Name</b>	Ethanol solution
<b>Hazard Class</b>	3
<b>Packing Group</b>	II

**IMDG**

<b>UN/ID No</b>	UN1170
<b>Proper Shipping Name</b>	Ethanol solution
<b>Hazard Class</b>	3
<b>Packing Group</b>	II

**15. REGULATORY INFORMATION****International Inventories**

Not determined

**US Federal Regulations****SARA 313**

Chemical Name	CAS No	Weight-%	SARA 313 - Threshold Values %
Isopropyl alcohol - 67-63-0	67-63-0	0.25	1.0



SDS DATE: 9/18/2015

**US State Regulations****California Proposition 65**

This product contains the following Proposition 65 chemicals.

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

**U.S. State Right-to-Know Regulations**

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Ethanol 64-17-5	X	X	X
Glycerol 56-81-5	X	X	X
Isopropyl alcohol 67-63-0	X	X	X

**16. OTHER INFORMATION****NFPA****Health Hazards**

Not determined

**Flammability**

Not determined

**Instability**

Not determined

**Special Hazards**

Not determined

**HMIS****Health Hazards**

0

**Flammability**

3

**Physical Hazards**

0

**Personal Protection**

0

**Issue Date**

23-JUN-2013

**Revision Date:**

18-SEP-2015

**Revision Note**

New format

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

CBW# 802900



# MATERIAL SAFETY DATA SHEET

## BAYER HEALTHCARE LLC

Consumer Care Division  
36 Columbia Road  
Morristown, NJ 07962-1910

**TRANSPORTATION EMERGENCY**  
CALL CHEMTREC..... : (800) 424-9300  
INTERNATIONAL ..... : (703) 527-3887

**NON-TRANSPORTATION**  
BAYER EMERGENCY PHONE : (800) 331-4536  
BAYER INFORMATION PHONE: (800) 331-4536  
or (800) 743-5423

### Section 1: Product and Company Identification

**Product Name:** Phillips' Milk of Magnesia - Original  
**Chemical Family:** Laxative

### Section 2: Composition/Information on Ingredients

#### HAZARDOUS INGREDIENTS

<u>Ingredient Name/</u> <u>CAS Number</u>	<u>Exposure Limits</u>	<u>Concentration</u>	
		<u>Min.</u>	<u>Max.</u>
This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.			

**Label Ingredients:** Magnesium Hydroxide; Water; Sodium Hypochlorite;

#### OTHER INGREDIENTS

The ingredients listed below are provided for informational purposes.

<u>Ingredient Name/</u> <u>CAS Number</u>	<u>Exposure Limits</u>	<u>Concentration</u>	
		<u>Min.</u>	<u>Max.</u>
Magnesium hydroxide 1309-42-8	OSHA (PEL): Not Established ACGIH (TLV): Not Established	5%	10%

### Section 3: Hazards Identification

Material Name: Phillips' Milk of Magnesia - Original

1 of 7

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### EMERGENCY OVERVIEW

**Color:** White **Form:** Liquid **Odor:** Odorless  
 Product poses little or no hazard if spilled and no unusual hazard if involved in a fire. See Potential Health Effects if the recommended dosage is exceeded.

### POTENTIAL HEALTH EFFECTS

**Route(s) of Entry:** Appropriate route of entry:, Ingestion

### HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE

#### Inhalation Hazards

**Acute Inhalation Hazards:** Not expected to be irritating.

#### Skin Hazards

**Acute Skin Hazards:** Not expected to be irritating.

#### Eye Hazards

**Acute Eye Hazards:** May cause slight irritation.

#### Ingestion Hazards

**Acute Ingestion Hazards:** Causes a laxative effect. Magnesia salts are so slowly absorbed that oral administration ordinarily causes only purging.

#### Carcinogenic Components:

**NTP:** None

**IARC:** None

**OSHA:** None

#### **Medical Conditions Aggravated by Exposure:**

Do not take this product without first consulting a health professional, if you have any of the following conditions: Taking prescription medications, a magnesium-restricted diet, Kidney disease, Consult a doctor before using a laxative if abdominal pain, nausea or vomiting are present, or there has been a sudden change in bowel habits that persists over a period of 2 weeks. Laxative products should not be used for a period longer than 1 week unless directed by a doctor. Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult your doctor.

#### **Human Health Effects Postnote:**

This is a pharmaceutical material available without a prescription. Use only as directed. See carton for full directions and warnings.

### Section 4: First Aid Measures

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

**First Aid for Skin:** In case of skin contact, wash affected areas with soap and water. Contact a physician if irritation develops.



**First Aid for Inhalation:** Not applicable.

**First Aid for Ingestion:** In case of overdose, contact your regional poison control center or physician immediately. Contact U.S. Poison Control Center at 1-800-222-1222.

#### Section 5: Fire Fighting Measures

**Flash Point:** Not Applicable

**Flammable Limits:**

**Upper Explosion Limit (UEL %):** Not Established

**Lower Explosion Limit (LEL %):** Not Established

**Auto-ignition Temperature:** Not Applicable

**Extinguishing Media:**

**Suitable:** Water

**Special Fire Fighting Procedures:** Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

#### Section 6: Accidental Release Measures

**Spill or Leak Procedures:** Absorb material and place in appropriate containers for disposal. Wash spill area with water. Spill area can be washed to a sanitary sewer.

#### Section 7: Handling and Storage

**Storage Temperature:** Room Temperature

**Shelf Life:** Do not use after expiration date.

**Special Sensitivity:** None known.

**Handling/Storage Precautions:** Keep out of reach of children. Avoid contact with eyes. Avoid excessive contact with skin or clothing. Wash thoroughly after handling. Store in a dry place away from excessive heat. Reseal containers immediately after use.

#### Section 8: Exposure Controls/Personal Protection

**Personal Protection Equipment**

<b>Eye Protection Requirements:</b>	None for normal use.
<b>Skin Protection Requirements:</b>	No special skin protection requirements during normal handling and use.
<b>Ventilation Requirements:</b>	Under normal conditions of use, special ventilation is not required.
<b>Respirator Requirements:</b>	Under normal conditions of use, respiratory protection is not required.
<b>Work Practices:</b>	Normal clinical practice. Use good personal hygiene - wash hands and exposed skin thoroughly with soap and water after each use.
<b>Additional Protective Measures:</b>	Employers shall provide handwashing facilities which are readily accessible to employees. Educate and train employees in the safe use and handling of this product.

**Section 9: Physical and Chemical Properties**

<b>Physical Form:</b>	Liquid
<b>Color:</b>	White
<b>Odor:</b>	Odorless
<b>pH:</b>	Not Applicable
<b>Boiling Point:</b>	Not Applicable
<b>Melting/Freezing Point:</b>	Not Established
<b>Solubility in Water:</b>	Not Applicable
<b>Specific Gravity:</b>	Not Applicable
<b>Bulk Density:</b>	Not Applicable
<b>Vapor Pressure:</b>	Not Applicable

**Section 10: Stability and Reactivity**

<b>Stability:</b>	Stable
<b>Hazardous Polymerization:</b>	Will not occur
<b>Substances to Avoid:</b>	See carton for full directions and warnings.
<b>Conditions to Avoid:</b>	None known.
<b>Decomposition Products:</b>	None known.

**Section 11: Toxicological Information****Toxicity Data for Phillips' Milk of Magnesia - Original**

**Toxicity Note:** No data available for this product.

### Section 12: Ecological Information

**Ecological Data for** Phillips' Milk of Magnesia - Original

**Ecological Note:** No data available for this product.

### Section 13: Disposal Considerations

**Waste Disposal Method:** Waste disposal should be in accordance with existing federal, state and local environmental control laws.

### Section 14: Transportation Information

**Technical shipping name:** Food grade ingredient mixture

#### Domestic Surface Transportation (DOT)

**Hazard Class or Division:** Non-Regulated

#### Marine Transportation (IMO / IMDG)

**Hazard Class Division** Non-Regulated  
**Number:**

#### Air Transportation (ICAO / IATA)

**Hazard Class Division** Non-Regulated  
**Number:**

### Section 15: Regulatory Information

#### United States Federal Regulations

**OSHA Hazcom Standard** Not subject to OSHA  
**Rating:**

**TSCA Inventory List:** This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical application.

#### **CERCLA Hazardous Substance:**

Component(s)  
None

Reportable Quantity

#### SARA Title III

#### **SARA Section 302 Extremely Hazardous Substances:**

Component(s)/  
CAS Number  
Exempt

Concentration  
Min. Max.

**SARA Section 311/312 Hazard** Exempt from SARA Section 311/312

Material Name: Phillips' Milk of Magnesia - Original

**Categories:****SARA Section 313 Toxic Chemicals:**

<u>Component(s)/</u> <u>CAS Number</u> Exempt	<u>Reporting</u> <u>Threshold</u>	<u>Concentration</u> <u>Min.</u> <u>Max.</u>
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**RCRA Status:**

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

The following chemicals are specifically listed by individual states; other product specific health and safety data in other sections of the MSDS may also be applicable for state requirements. For details on your regulatory requirements you should contact the appropriate agency in your state.

**State Right-to-Know Information**

<u>Component(s)/</u> <u>CAS Number</u>	<u>State Code</u>	<u>Concentration</u> <u>Min.</u> <u>Max.</u>
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State Code Translation Table

**Section 16: Other Information****HMIS Rating**

<b>Health</b>	0
<b>Flammability</b>	0
<b>Reactivity</b>	0

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe

\*=Chronic Health Hazard

BAYER HEALTHCARE LLC's method of hazard communication is comprised of Product Labels and Material Safety Data Sheets. HMIS and NFPA ratings are provided by BAYER HEALTHCARE LLC as a customer service.

Contact: Phil Cornejo  
Phone: 717-866-3855  
MSDS Number: 000000001862  
Version Date: 11/29/2007  
MSDS Version: 1.4

This information is furnished without warranty, expressed or implied, except that it is accurate to the best knowledge of BAYER HEALTHCARE LLC. The data on this sheet relates only to the specific material designated herein. BAYER HEALTHCARE LLC assumes no legal responsibility for use or reliance upon these data.

|| Indicates Relevant Change Made.

Material Name: Phillips' Milk of Magnesia - Original







# Nitrogen, refrigerated liquid

## Safety Data Sheet P-4630

This SDS conforms to U.S. Code of Federal Regulations 29 CFR 1910.1200, Hazard Communication.  
Date of issue: 01/01/1979 Revision date: 10/21/2016 Supersedes: 10/03/2014

### SECTION: 1. Product and company identification

#### 1.1. Product identifier

Product form : Substance  
Name : Nitrogen, refrigerated liquid  
CAS No : 7727-37-9  
Formula : N<sub>2</sub>  
Other means of identification : Nitrogen (cryogenic liquid), Nitrogen, Medipure Liquid Nitrogen

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

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

#### 1.3. Details of the supplier of the safety data sheet

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

#### 1.4. Emergency telephone number

Emergency number : Onsite Emergency: 1-800-645-4633

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

### SECTION 2: Hazard identification

#### 2.1. Classification of the substance or mixture

##### GHS-US classification

Refrigerated liquefied gas H281

#### 2.2. Label elements

##### GHS-US labeling

Hazard pictograms (GHS-US) :



GHS04

Signal word (GHS-US) :

WARNING

Hazard statements (GHS-US) :

H281 - CONTAINS REFRIGERATED GAS; MAY CAUSE CRYOGENIC BURNS OR INJURY  
OSHA-H01 - MAY DISPLACE OXYGEN AND CAUSE RAPID SUFFOCATION

Precautionary statements (GHS-US) :

P202 - Do not handle until all safety precautions have been read and understood  
P271+P403 - Use and store only outdoors or in a well-ventilated place  
P282 - Wear cold insulating gloves/face shield/eye protection. cold insulating gloves, face shield, eye protection  
CGA-PG05 - Use a back flow preventive device in the piping  
CGA-PG24 - DO NOT change or force fit connections  
CGA-PG06 - Close valve after each use and when empty  
CGA-PG23 - Always keep container in upright position

#### 2.3. Other hazards

Other hazards not contributing to the : Asphyxiant in high concentrations



# Nitrogen, refrigerated liquid

## Safety Data Sheet P-4630

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

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

classification Contact with liquid may cause cold burns/frostbite.

### 2.4. Unknown acute toxicity (GHS US)

No data available

## SECTION 3: Composition/Information on ingredients

### 3.1. Substance

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

### 3.2. Mixture

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures after inhalation : Remove victim to uncontaminated area wearing self contained breathing apparatus. Keep victim warm and rested. Call a doctor. Apply artificial respiration if breathing stopped.
- First-aid measures after skin contact : The liquid may cause frostbite. For exposure to liquid, immediately warm frostbite area with warm water not to exceed 105°F (41°C). Water temperature should be tolerable to normal skin. Maintain skin warming for at least 15 minutes or until normal coloring and sensation have returned to the affected area. In case of massive exposure, remove clothing while showering with warm water. Seek medical evaluation and treatment as soon as possible.
- First-aid measures after eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes. Hold the eyelids open and away from the eyeballs to ensure that all surfaces are flushed thoroughly. Contact an ophthalmologist immediately.. Get immediate medical attention.
- First-aid measures after ingestion : Ingestion is not considered a potential route of exposure.

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

No additional information available

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

None.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

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

### 5.2. Special hazards arising from the substance or mixture

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

### 5.3. Advice for firefighters

- Firefighting instructions : DANGER! Extremely cold liquid and gas under pressure. Take care not to direct spray onto vents on top of container. Do not discharge sprays directly into liquid; cryogenic liquid can freeze water rapidly
- Evacuate all personnel from the danger area. Use self-contained breathing apparatus (SCBA) and protective clothing. Immediately cool containers with water from maximum distance. Stop flow of gas if safe to do so, while continuing cooling water spray. Remove ignition sources if safe to do so. Remove containers from area of fire if safe to do so. On-site fire brigades must comply with OSHA 29 CFR 1910.156 and applicable standards under 29 CFR 1910 Subpart L—Fire Protection.
- Protection during firefighting : Compressed gas: asphyxiant. Suffocation hazard by lack of oxygen.
- Special protective equipment for fire fighters : Use self-contained breathing apparatus. Standard protective clothing and equipment (Self Contained Breathing Apparatus) for fire fighters.





# Nitrogen, refrigerated liquid

## Safety Data Sheet P-4630

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

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

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

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

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

##### 6.1.1. For non-emergency personnel

No additional information available

##### 6.1.2. For emergency responders

No additional information available

#### 6.2. Environmental precautions

Try to stop release.

#### 6.3. Methods and material for containment and cleaning up

No additional information available

#### 6.4. Reference to other sections

See also sections 8 and 13.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

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



# Nitrogen, refrigerated liquid

## Safety Data Sheet P-4630

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

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

### 7.2. Conditions for safe storage, including any incompatibilities

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

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

### 7.3. Specific end use(s)

None.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

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

### 8.2. Exposure controls

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

Hand protection : Wear working gloves when handling gas containers.

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

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

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

Environmental exposure controls : None necessary.

Other information : Wear safety shoes while handling containers.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Gas

Appearance : Colorless liquid.

Molecular mass : 28 g/mol

Color : Colorless liquid.

Odor : No odor warning properties.

Odor threshold : No data available

pH : Not applicable.

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

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

Melting point : -210 °C

Freezing point : No data available

Boiling point : -195.8 °C

Flash point : No data available

Critical temperature : -149.9 °C



# Nitrogen, refrigerated liquid

## Safety Data Sheet P-4630

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

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

Auto-ignition temperature	: Not applicable.
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: Not applicable.
Critical pressure	: 3390 kPa
Relative vapor density at 20 °C	: No data available
Relative density	: 0.8
Density	: 808.5 kg/m <sup>3</sup> Liquid density at boiling point and 1 atm
Relative gas density	: 0.97
Solubility	: Water: 20 mg/l
Log Pow	: Not applicable.
Log Kow	: Not applicable.
Viscosity, kinematic	: Not applicable.
Viscosity, dynamic	: Not applicable.
Explosive properties	: Not applicable.
Oxidizing properties	: None.
Explosion limits	: No data available

### 9.2. Other information

Gas group	: Refrigerated liquefied gas
Additional information	: Gas/vapor heavier than air. May accumulate in confined spaces, particularly at or below ground level

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

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

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None.

### 10.4. Conditions to avoid

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

### 10.5. Incompatible materials

None.

### 10.6. Hazardous decomposition products

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

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

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

EN (English US)

SDS ID: P-4630

5/9





# Nitrogen, refrigerated liquid

## Safety Data Sheet P-4630

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

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

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

Emergency Response Guide (ERG) Number	: 121 (UN1066);120 (UN1977)
Other information	: No supplementary information available.
Special transport precautions	<p>: Avoid transport on vehicles where the load space is not separated from the driver's compartment. Ensure vehicle driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency. Before transporting product containers:</p> <ul style="list-style-type: none"> <li>- Ensure there is adequate ventilation. - Ensure that containers are firmly secured. - Ensure cylinder valve is closed and not leaking. - Ensure valve outlet cap nut or plug (where provided) is correctly fitted. - Ensure valve protection device (where provided) is correctly fitted.</li> </ul>

### Transport by sea

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

### Air transport

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

## SECTION 15: Regulatory information

### 15.1. US Federal regulations

Nitrogen, refrigerated liquid (7727-37-9)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
SARA Section 311/312 Hazard Classes	<p>Immediate (acute) health hazard</p> <p>Sudden release of pressure hazard</p>
All components of this product are listed on the Toxic Substances Control Act (TSCA) inventory.	



# Nitrogen, refrigerated liquid

## Safety Data Sheet P-4630

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

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

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

### 15.2. International regulations

#### CANADA

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

### EU-Regulations

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

### 15.2.2. National regulations

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

### 15.3. US State regulations

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

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



# Nitrogen, refrigerated liquid

## Safety Data Sheet P-4630

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

### SECTION 16: Other information

#### Other information

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

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

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

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

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#### NFPA health hazard

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

#### NFPA fire hazard

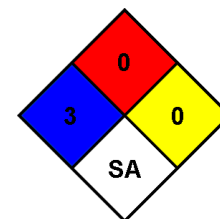
: 0 - Materials that will not burn.

#### NFPA reactivity

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

#### NFPA specific hazard

: SA - This denotes gases which are simple asphyxiants.



### HMIS III Rating

#### Health

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

#### Flammability

: 0 Minimal Hazard

#### Physical

: 2 Moderate Hazard

SDS US (GHS HazCom 2012) - Praxair

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





 <b>YARA</b>  <b>YARA PRAXAIR</b>	<b>SAFETY DATA SHEET</b>	Page : 1 / 9
		Revised edition no : 1
		Date : 31 / 1 / 2013
		Supersedes : 0 / 0 / 0
<b>Oxygen</b>		<b>YPX097A</b>



2.2 : Non-flammable, non-toxic gases



**Danger**



## SECTION 1. Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Trade name	: Oxygen ; Oxygen Lazer P; Medical Oxygen; Mapcon Oxygen
SDS Nr	: YPX097A . (Replaces EIGA097A, 23.02.2010.)
Chemical description	: Oxygen CAS No :7782-44-7 EC No :231-956-9 Index No :008-001-00-8
Registration-No.	: Listed in Annex IV / V REACH, exempted from registration.
Chemical formula	: O <sub>2</sub>

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

Relevant identified uses	: Industrial and professional. Perform risk assessment prior to use. Test gas/Calibration gas. Laboratory use. Shield gas for welding processes. Laser gas. Plasma gas. Combustion processes. Food applications. Medical applications. Water treatment. Use for manufacture of electronic/photovoltaic components. Contact supplier for more information on uses.
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### 1.3. Details of the supplier of the safety data sheet


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

### 1.4. Emergency telephone number

Emergency telephone number	: 22 59 13 00 [24 t - Giftinformasjonssentralen] 48 00 50 00 [24 t - Beredskapstelefon Yara Praxair]
----------------------------	---

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	SAFETY DATA SHEET	Page : 2 / 9
		Revised edition no : 1
		Date : 31 / 1 / 2013
		Supersedes : 0 / 0 / 0
Oxygen		YPX097A

## SECTION 2. Hazards identification

### 2.1. Classification of the substance or mixture

#### Hazard Class and Category Code Regulation EC 1272/2008 (CLP)

- Physical hazards : Oxidizing gases - Category 1 - Danger - (CLP : Ox. Gas 1) - H270  
Gases under pressure - Compressed gas - Warning - (CLP : Press. Gas) - H280

#### Classification EC 67/548 or EC 1999/45

: O; R8

### 2.2. Label elements

#### Labelling Regulation EC 1272/2008 (CLP)

- Hazard pictograms



- Hazard pictograms code : GHS03 - GHS04
- Signal word : Danger
- Hazard statements : H270 - May cause or intensify fire; oxidiser.  
H280 - Contains gas under pressure; may explode if heated.
- Precautionary statements
  - Prevention : P244 - Keep valves and fittings free from oil and grease  
P220 - Keep away from combustible materials.
  - Response : P370+P376 - In case of fire : Stop leak if safe to do so.
  - Storage : P403 - Store in a well-ventilated place.

### 2.3. Other hazards

: None.

## SECTION 3. Composition/information on ingredients

### 3.1. Substance / 3.2. Mixture

Substance.

Substance name	Contents	CAS No EC No Index No Registration no	Classification(DSD)	Classification(CLP)
Oxygen	: 100 %	7782-44-7 231-956-9 008-001-00-8 * 1	O; R8	Ox. Gas 1 (H270) Press. Gas Compressed (H280)

Contains no other components or impurities which will influence the classification of the product.

\* 1: Listed in Annex IV / V REACH, exempted from registration.

\* 2: Registration deadline not expired.

\* 3: Registration not required: Substance manufactured or imported < 1t/y.


Full text of R-phrases see section 16. Full text of H-statements see section 16.

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  <b>YARA</b> <b>PRAXAIR</b>	<b>SAFETY DATA SHEET</b>	Page : 3 / 9
		Revised edition no : 1
		Date : 31 / 1 / 2013
		Supersedes : 0 / 0 / 0
<b>Oxygen</b>		<b>YPX097A</b>

#### SECTION 4. First aid measures

##### 4.1. Description of first aid measures

- Inhalation : Remove victim to uncontaminated area.
- Skin contact : Adverse effects not expected from this product.
- Eye contact : Adverse effects not expected from this product.
- Ingestion : Ingestion is not considered a potential route of exposure.

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

- : Continuous inhalation of concentrations higher than 75% may cause nausea, dizziness, respiratory difficulty and convulsion.

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

- : None.

#### SECTION 5. Firefighting measures

##### 5.1. Extinguishing media

- Suitable extinguishing media : Water spray or fog.
- Unsuitable extinguishing media : Do not use water jet to extinguish.

##### 5.2. Special hazards arising from the substance or mixture

- Specific hazards : Exposure to fire may cause containers to rupture/explode. Supports combustion.
- Hazardous combustion products : None.

##### 5.3. Advice for fire-fighters

- Specific methods : Use fire control measures appropriate for the surrounding fire. Exposure to fire and heat radiation may cause gas receptacles to rupture. Cool endangered receptacles with water spray jet from a protected position. Prevent water used in emergency cases from entering sewers and drainage systems. If possible, stop flow of product. Use water spray or fog to knock down fire fumes if possible.
- Special protective equipment for fire fighters : Standard protective clothing and equipment (Self Contained Breathing Apparatus) for fire fighters. Standard EN 137 - Self-contained open-circuit compressed air breathing apparatus with full face mask. Standard EN 469 - Protective clothing for firefighters. Standard - EN 659: Protective gloves for firefighters.

#### SECTION 6. Accidental release measures

##### 6.1. Personal precautions, protective equipment and emergency procedures

- : Try to stop release. Ensure adequate air ventilation. Prevent from entering sewers, basements and workpits, or any place where its accumulation can be dangerous. Monitor concentration of released product. Eliminate ignition sources. Evacuate area.

##### 6.2. Environmental precautions


- : Try to stop release.

##### 6.3. Methods and material for containment and cleaning up

- : Ventilate area.

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	SAFETY DATA SHEET	Page : 4 / 9
		Revised edition no : 1
		Date : 31 / 1 / 2013
		Supersedes : 0 / 0 / 0
Oxygen		YPX097A

## SECTION 6. Accidental release measures (continued)

### 6.4. Reference to other sections

: See also sections 8 and 13.

## SECTION 7. Handling and storage

### 7.1. Precautions for safe handling

#### Safe use of the product

: Only experienced and properly instructed persons should handle gases under pressure. The substance must be handled in accordance with good industrial hygiene and safety procedures.  
Use only properly specified equipment which is suitable for this product, its supply pressure and temperature. Contact your gas supplier if in doubt.  
Use no oil or grease.  
Do not smoke while handling product.  
Keep equipment free from oil and grease.  
Use only oxygen approved lubricants and oxygen approved sealings.  
Use only with equipment cleaned for oxygen service and rated for cylinder pressure.  
Ensure the complete gas system was (or is regularly) checked for leaks before use.  
Consider pressure relief device(s) in gas installations.

#### Safe handling of the gas receptacle

: Refer to supplier's container handling instructions.  
Suck back of water into the container must be prevented.  
Open valve slowly to avoid pressure shock.  
Do not allow backfeed into the container.  
Protect cylinders from physical damage; do not drag, roll, slide or drop.  
When moving cylinders, even for short distances, use a cart (trolley, hand truck, etc.) designed to transport cylinders.  
Leave valve protection caps in place until the container has been secured against either a wall or bench or placed in a container stand and is ready for use.  
If user experiences any difficulty operating cylinder valve discontinue use and contact supplier.  
Never attempt to repair or modify container valves or safety relief devices.  
Damaged valves should be reported immediately to the supplier.  
Keep container valve outlets clean and free from contaminants particularly oil and water.  
Replace valve outlet caps or plugs and container caps where supplied as soon as container is disconnected from equipment.  
Close container valve after each use and when empty, even if still connected to equipment.  
Never attempt to transfer gases from one cylinder/container to another.  
Never use direct flame or electrical heating devices to raise the pressure of a container.  
Do not remove or deface labels provided by the supplier for the identification of the cylinder contents.

### 7.2. Conditions for safe storage, including any incompatibilities

: Keep container below 50°C in a well ventilated place.  
Segregate from flammable gases and other flammable materials in store. Containers should be stored in the vertical position and properly secured to prevent toppling. Stored containers should be periodically checked for general condition and leakage. Container valve guards or caps should be in place. Store containers in location free from fire risk and away from sources of heat and ignition.  
Containers should not be stored in conditions likely to encourage corrosion. Keep away from combustible materials.

### 7.3. Specific end use(s)


: None.

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	SAFETY DATA SHEET	Page : 5 / 9
		Revised edition no : 1
		Date : 31 / 1 / 2013
		Supersedes : 0 / 0 / 0
Oxygen		YPX097A

## SECTION 8. Exposure controls/personal protection

### 8.1. Control parameters

DNEL: Derived no effect level (Workers)

: No data available.

PNEC: Predicted no effect concentration

: No data available.

### 8.2. Exposure controls

8.2.1. Appropriate engineering controls

: Systems under pressure should be regularly checked for leakages.  
Avoid oxygen rich (>23,5%) atmospheres.  
Gas detectors should be used when oxidising gases may be released.  
Provide adequate general and local exhaust ventilation.  
Consider work permit system e.g. for maintenance activities.

8.2.2. Individual protection measures, e.g. personal protective equipment

: PPE compliant to the recommended EN/ISO standards should be selected.  
A risk assessment should be conducted and documented in each work area to assess the risks related to the use of the product and to select the PPE that matches the relevant risk.  
The following recommendations should be considered:  
Wear suitable hand, body and head protection. Wear goggles with suitable filter lenses when use is cutting/welding.

• Eye/face protection

: Wear safety glasses with side shields.  
Standard EN 166 - Personal eye-protection.

• Skin protection

- Hand protection

: Wear working gloves when handling gas containers.  
Standard EN 388 - Protective gloves against mechanical risk.

- Other

: Wear safety shoes while handling containers.  
Standard EN ISO 20345 - Personal protective equipment - Safety footwear.  
Standard EN ISO 14116 - Limited flame spread materials.  
Consider the use of flame resistant safety clothing.

• Respiratory protection

: None necessary.

• Thermal hazards

: None necessary.

8.2.3. Environmental exposure controls

: None necessary.

## SECTION 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Appearance

Physical state at 20°C / 101.3kPa : Gas.

Colour : Colourless.

Odour : No odour warning properties.

Odour threshold : Odour threshold is subjective and inadequate to warn for overexposure.

pH value : Not applicable.

Molar mass [g/mol] : 32

Melting point [°C] : -219

Boiling point [°C] : -183

Critical temperature [°C] : -118

Flash point [°C] : Not applicable for gases and gas-mixtures.

Evaporation rate (ether=1) : Not applicable for gases and gas-mixtures.


Flammability range [vol% in air] : Non flammable.

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 <b>YARA</b>  <b>YARA PRAXAIR</b>	<b>SAFETY DATA SHEET</b>	Page : 6 / 9
		Revised edition no : 1
		Date : 31 / 1 / 2013
		Supersedes : 0 / 0 / 0
<b>Oxygen</b>		<b>YPX097A</b>

## SECTION 9. Physical and chemical properties (continued)

Vapour pressure [20°C]	: Not applicable.
Relative density, gas (air=1)	: 1.1
Relative density, liquid (water=1)	: 1.1
Solubility in water [mg/l]	: 39
Partition coefficient n-octanol/water [log Kow]	: Not applicable for inorganic gases.
Auto-ignition temperature [°C]	: Not applicable.
Viscosity at 20°C [mPa.s]	: Not applicable.
Explosive Properties	: Not applicable.
Oxidising Properties	: Oxidiser.
- Coefficient of oxygen equivalency (Ci)	: 1

### 9.2. Other information

Other data	: Gas/vapour heavier than air. May accumulate in confined spaces, particularly at or below ground level.
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## SECTION 10. Stability and reactivity

### 10.1. Reactivity

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

### 10.2. Chemical stability

: Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

: Violently oxidises organic material.

### 10.4. Conditions to avoid

: None under recommended storage and handling conditions (see section 7).

### 10.5. Incompatible materials

: Consider the potential toxicity hazard due to the presence of chlorinated or fluorinated polymers in high pressure (> 30 bar) oxygen lines in case of combustion.  
May react violently with combustible materials.  
May react violently with reducing agents.  
Keep equipment free from oil and grease.  
For additional information on compatibility refer to ISO 11114.

### 10.6. Hazardous decomposition products

: None.

## SECTION 11. Toxicological information

### 11.1. Information on toxicological effects


Acute toxicity	: No known toxicological effects from this product.
Skin corrosion/irritation	: No known effects from this product.
Serious eye damage/irritation	: No known effects from this product.
Respiratory or skin sensitisation	: No known effects from this product.
Carcinogenicity	: No known effects from this product.
Germ cell mutagenicity	: No known effects from this product.

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	SAFETY DATA SHEET	Page : 7 / 9
		Revised edition no : 1
		Date : 31 / 1 / 2013
		Supersedes : 0 / 0 / 0
Oxygen		YPX097A

#### SECTION 11. Toxicological information (continued)

Reproductive toxicity	: No known effects from this product.
STOT-single exposure	: No known effects from this product.
STOT-repeated exposure	: No known effects from this product.
Aspiration hazard	: Not applicable for gases and gas-mixtures.

#### SECTION 12. Ecological information

##### 12.1. Toxicity

: No ecological damage caused by this product.

##### 12.2. Persistence and degradability

: No ecological damage caused by this product.

##### 12.3. Bioaccumulative potential

: No ecological damage caused by this product.

##### 12.4. Mobility in soil

: No ecological damage caused by this product.

##### 12.5. Results of PBT and vPvB assessment

: Not classified as PBT or vPvB.

##### 12.6. Other adverse effects

Effect on ozone layer	: None.
Effect on the global warming	: No known effects from this product.

#### SECTION 13. Disposal considerations

##### 13.1. Waste treatment methods

: May be vented to atmosphere in a well ventilated place.  
Do not discharge into any place where its accumulation could be dangerous.  
Refer to the EIGA code of practice Doc.30 "Disposal of Gases", downloadable at <http://www.eiga.org> for more guidance on suitable disposal methods.

List of hazardous waste codes (from Commission Decision 2001/118/EC) : 16 05 04: Gases in pressure containers (including halons) containing dangerous substances.

##### 13.2. Additional information

: None.

#### SECTION 14. Transport information

UN number : 1072  
Labelling ADR, IMDG, IATA




: 5.1 : Oxidizing substances  
2.2 : Non-flammable, non-toxic gases

##### Land transport (ADR/RID)

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 <b>YARA</b>  <b>YARA</b> <b>PRAXAIR</b>	<b>SAFETY DATA SHEET</b>	Page : 8 / 9
		Revised edition no : 1
		Date : 31 / 1 / 2013
		Supersedes : 0 / 0 / 0
<b>Oxygen</b>		<b>YPX097A</b>

#### SECTION 14. Transport information (continued)

H.I. nr : 25  
 UN proper shipping name : OXYGEN, COMPRESSED  
 Transport hazard class(es) : 2  
 Classification code : 1 O  
 Packing group : -  
 Packing Instruction(s) : P200  
 Tunnel Restriction : E : Passage forbidden through tunnels of category E.  
 Environmental hazards : None.

##### Sea transport (IMDG)

Proper shipping name : OXYGEN, COMPRESSED  
 Class : 2.2  
 Emergency Schedule (EmS) - Fire : F-C  
 Emergency Schedule (EmS) - Spillage : S-W  
 Packing instruction : P200  
 IMDG-Marine pollutant : No

##### Air transport (ICAO-TI / IATA-DGR)

Proper shipping name (IATA) : OXYGEN, COMPRESSED  
 Class : 2.2  
 Passenger and Cargo Aircraft : Allowed.  
 Packing instruction - Passenger and Cargo Aircraft : 200  
 Cargo Aircraft only : Allowed.  
 Packing instruction - Cargo Aircraft only : 200

##### Special precautions for user

: Avoid transport on vehicles where the load space is not separated from the driver's compartment.  
 Ensure vehicle driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency.  
 Before transporting product containers:  
 - Ensure that containers are firmly secured.  
 - Ensure cylinder valve is closed and not leaking.  
 - Ensure valve outlet cap nut or plug (where provided) is correctly fitted.  
 - Ensure valve protection device (where provided) is correctly fitted.  
 - Ensure there is adequate ventilation.  
 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not applicable.

#### SECTION 15. Regulatory information

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

###### EU legislation

Restrictions on use : None.  
 Seveso directive 96/82/EC : Listed.

###### National legislation


National legislation : Ensure all national/local regulations are observed.

##### 15.2. Chemical safety assessment

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

#### SECTION 15. Regulatory information (continued)

: A CSA does not need to be carried out for this product.

#### SECTION 16. Other information

<b>Indication of changes</b>	: Revised safety data sheet in accordance with commission regulation (EU) No 453/2010.
<b>Training advice</b>	: Ensure operators understand the hazard of oxygen enrichment.
<b>List of full text of R-phrases in section 3.</b>	: R8 : Contact with combustible material may cause fire.
<b>List of full text of H-statements in section 3.</b>	: H270 - May cause or intensify fire; oxidiser. H280 - Contains gas under pressure; may explode if heated.
<b>Further information</b>	: This Safety Data Sheet has been established in accordance with the applicable European Union legislation.
<b>DISCLAIMER OF LIABILITY</b>	: Before using this product in any new process or experiment, a thorough material compatibility and safety study should be carried out. Details given in this document are believed to be correct at the time of going to press. Whilst proper care has been taken in the preparation of this document, no liability for injury or damage resulting from its use can be accepted.

**End of document**

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## SAFETY DATA SHEET

PRODUCT NAME: PNEUMOVAX™ 23

Page: 1/6

Revision 1-Apr-2010

### 1. Product and Company Identification

<u>Manufactured/Supplied by</u>	Merck Sharp & Dohme Corp. A wholly owned subsidiary of Merck & Co., Inc. One Merck Drive Whitehouse Station, NJ 08889-0100 (908) 423-1000 (General Information Only)
<u>Label Name</u>	<b>Emergency Telephone Number:</b> 1-908-423-6000 (24/7/365) English Only PNEUMOVAX™ 23
<u>Chemical Name</u>	Pneumococcal vaccine polyvalent
<u>Synonyms</u>	Not available
<u>Material Product Number</u>	4739 - One 5-dose vial of liquid vaccine. 4943 - Single-dose vial of liquid vaccine in a box of 10 single-dose vials. <b>NDC 0006-4739-00</b> <b>NDC 0006-4943-00</b>
<u>Intended Use</u>	Vaccine indicated for vaccination against pneumococcal disease caused by those pneumococcal types included in the vaccine.

### 2. Composition/Information on Ingredients

<u>Component</u>	<u>Molecular Formula</u>	<u>Molecular weight</u>	<u>CAS Number</u>	<u>Percent (%)</u>
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

<u>Appearance</u>	Clear, colorless solution
<u>Label Text</u>	CAUTION! VACCINE
<u>Emergency Overview</u>	No specific hazard with intact vials.  Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.
<u>Potential Health Effects</u>	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<sub>2</sub>.

##### 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).

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 2-8°C (35.6-46.4°F)

**8. Exposure Controls/Personal Protection**Exposure Guidelines

<u>Component</u>	<u>OSHA Permissible Exposure Limit (PEL)</u>	<u>ACGIH Threshold Limit Value (TLV)</u>	<u>Merck Exposure Control Limit (ECL) or PB-ECL Category</u>
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 <sup>3</sup> (8-hr TWA)
Inactive ingredients	Not available	Not available	Not established

ADI = 100 ug/day

Wipe Test Criteria = 100 ug/cm<sup>2</sup>

**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.

## 9. Physical and Chemical Properties

<u>Appearance</u>	Clear, colorless solution
<u>Odor/Threshold Limit</u>	Not available
<u>pH</u>	Not available
<u>Boiling Point</u>	Not available
<u>Melting Point</u>	Not available
<u>Flash point</u>	Not applicable
<u>Flammable Limits (% in air)</u>	Not applicable
<u>Autoignition Temperature</u>	Not available
<u>Solubility</u>	Not available
<u>Partition Coefficient</u>	Not available
<u>Specific Gravity</u>	Not available
<u>Vapor Density</u>	Not available
<u>Vapor Pressure</u>	Not available
<u>Volatility Component</u>	Not available

## 10. Stability and Reactivity

<u>Stability</u>	Not available
<u>Conditions to Avoid</u>	Not available
<u>Incompatibility</u>	Not available
<u>Hazardous Polymerization</u>	Not available
<u>Hazardous Decomposition Products</u>	None known.

## 11. Toxicological Information

<u>Routes of Entry</u>	Ingestion:	No.
	Inhalation:	Yes
	Skin Contact:	No.

### Toxicity Data

<u>Component</u>	<u>Test</u>	<u>Species</u>	<u>Route</u>	<u>Result</u>
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

<u>Eye contact</u>	Non-irritating to the eyes.
<u>Skin contact</u>	Not available
<u>Inhalation</u>	Not available
<u>Ingestion</u>	Not available

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 (<102°F). 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 DataComponentSpeciesPeriodResult

Pneumococcal Types  
1, 2, 3, 4, 5, 6B, 7F, 8,  
9N, 9V, 10A, 11A, 12F,  
14, 15B, 17F, 18C, 19A,  
19F, 20, 22F, 23F  
Inactive ingredients

Not available

Not available

Not available

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 DescriptionU.S. DOT

Not regulated.

IATA/ICAO

Not regulated.

IMO

Not regulated.

ADR/RID

Not regulated.

**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 subsidiary 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

## Potassium Hydroxide

Page: 1

Revision: 10/01/2013  
Supersedes Revision: 01/10/2013Cayman Chemical Company  
1180 E. Ellsworth Rd.  
Ann Arbor, MI 48108

### Section 1. Identification of the Substance/Mixture and of the

- 1.1 Product Code:** 400029  
**Product Name:** Potassium Hydroxide
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**  
**Relevant identified uses:** For research use only, not for human or veterinary use.
- 1.3 Details of the Supplier of the Safety Data Sheet**  
**Company Name:** Cayman Chemical Company  
**Emergency Contact:** CHEMTREC Within USA and Canada: +1 (800)424-9300  
**Alternate Emergency Contact:** CHEMTREC Outside USA and Canada: +1 (703)527-3887  
**Information:** Cayman Chemical Company +1 (734)971-3335  
**Web site address:** www.caymanchem.com

### Section 2. Hazards Identification

GHS Classification	Placard	Key word	GHS hazard phrase
Acute Toxicity: Oral, Category 4	Exclamation point	Warning	Harmful if swallowed
Skin Corrosion/Irritation, Category 1A	Corrosive	Danger	Causes severe skin burns and eye damage

- GHS Hazard Phrases:**  
H302: Harmful if swallowed.  
H314: Causes severe skin burns and eye damage.
- GHS Precaution Phrases:**  
P264: Wash {hands} thoroughly after handling.  
P260: Do not breathe {dust/fume/gas/mist/vapours/spray}.  
P280: Wear {protective gloves/protective clothing/eye protection/face protection}.
- GHS Response Phrases:**  
P301+312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.  
P330: Rinse mouth.  
P303+361+353: IF ON SKIN (or hair): Remove/take off immediately all contaminated clothing. Rinse skin with water/shower.  
P363: Wash contaminated clothing before reuse.  
P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P301+330+331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  
P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
P310: Immediately call a {POISON CENTER/doctor/...}.
- GHS Storage and Disposal Phrases:**  
Please refer to Section 7 for Storage and Section 13 for Disposal information.
- 2.3 Adverse Human Health Effects and Symptoms:**  
Causes severe skin burns.  
Causes serious eye damage.  
Harmful if swallowed, inhaled, or absorbed through the skin.  
Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract, eyes, and skin.  
To the best of our knowledge, the toxicological properties have not been thoroughly investigated.
- Target Organs:**  
Eyes, Respiratory system, Skin.
- LD 50 / LC 50:**  
Please refer to Section 11.



# SAFETY DATA SHEET

## Potassium Hydroxide

Page: 2

Revision: 10/01/2013  
Supersedes Revision: 01/10/2013

Medical Conditions Generally Aggravated By Exposure: No data available.

### Section 3. Composition/Information on Ingredients

Hazardous Components (Chemical Name)	CAS #	Concentration	EC#	Risk Phrases	RTECS #
1. Potassium hydroxide	1310-58-3	100.0 %	215-181-3	R22-35	TT2100000

### Section 4. First Aid Measures

#### 4.1 Description of First Aid Measures:

- 4.1.1 In Case of Inhalation:** Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
- 4.1.2 In Case of Skin Contact:** Immediately wash skin with soap and plenty of water for at least 20 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
- 4.1.3 In Case of Eye Contact:** Hold eyelids apart and flush eyes with plenty of water for at least 20 minutes. Have eyes examined and tested by medical personnel.
- 4.1.4 In Case of Ingestion:** Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.
- 4.2 Important Symptoms and Effects, Both Acute and Delayed:** Exposure can cause: burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea, and vomiting.  
Inhalation may result in spasm, inflammation, and edema of the larynx and bronchi, chemical pneumonitis, and pulmonary edema.
- 4.3 Indication of any immediate medical attention and special treatment needed:** No data available.

### Section 5. Fire Fighting Measures

- 5.1 Suitable Extinguishing Media:** Use alcohol-resistant foam, carbon dioxide, or dry chemical spray.
- Unsuitable Extinguishing Media:** DO NOT USE WATER.
- 5.2 Flammable Properties and Hazards:** Emits toxic fumes under fire conditions.  
May react with metals, releasing flammable hydrogen gas.
- Flash Pt:** No data.
- Autoignition Pt:** No data available.
- Explosive Limits:** LEL: No data. UEL: No data.
- Hazardous Combustion Products:** No data available.
- 5.3 Fire Fighting Instructions:** As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

### Section 6. Accidental Release Measures

- 6.1 Protective Precautions, Protective Equipment and Emergency Procedures:** Avoid raising and breathing dust, and provide adequate ventilation.  
As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).
- 6.2 Environmental Precautions:** Take steps to avoid release into the environment, if safe to do so.
- 6.3 Methods and Material For Containment and Cleaning Up:** Contain spill and collect, as appropriate.  
Transfer to a chemical waste container for disposal in accordance with local regulations.

### Section 7. Handling and Storage

- 7.1 Precautions To Be Taken in Handling:** Avoid breathing dust/fume/gas/mist/vapours/spray.  
Avoid prolonged or repeated exposure.



# SAFETY DATA SHEET

## Potassium Hydroxide

Page: 3

Revision: 10/01/2013  
Supersedes Revision: 01/10/2013

<b>7.2 Precautions To Be Taken in Storing:</b>	Keep container tightly closed. Store in accordance with information listed on the product insert.
<b>Other Precautions:</b>	Air sensitive. Hygroscopic.
<b>Hazard Label Information:</b>	Avoid contact with skin and eyes. Do not reuse this container. Use with adequate ventilation. Wash thoroughly after handling.

### Section 8. Exposure Controls/Personal Protection

Hazardous Components (Chemical Name)	CAS #	OSHA PEL	ACGIH TWA	Other Limits
1. Potassium hydroxide	1310-58-3	No data.	CEIL: 2 mg/m3	No data.
Hazardous Components (Chemical Name)	CAS #	Britain EH40	France VL	Europe
1. Potassium hydroxide	1310-58-3	STEL: 2 mg/m3 ( )	STEL: 2.0 mg/m3	No data.
<b>Protective Equipment Summary - Hazard Label Information:</b>	Compatible chemical-resistant gloves    Eye wash station in work area    Lab coat    Safety glasses    Safety shower in work area    Vent Hood			
<b>8.2.1 Engineering Controls (Ventilation etc.):</b>	Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.			
<b>8.2.2.1 Eye Protection:</b>	Safety glasses			
<b>8.2.2.2 Protective Gloves:</b>	Compatible chemical-resistant gloves			
<b>Other Protective Clothing:</b>	Lab coat			
<b>8.2.2.3 Respiratory Equipment (Specify Type):</b>	NIOSH approved respirator, as conditions warrant.			
<b>Work/Hygienic/Maintenance Practices:</b>	Do not take internally. Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Wash thoroughly after handling.			
<b>8.2.3 Environmental Exposure Controls:</b>	No data available.			

### Section 9. Physical and Chemical Properties

#### 9.1 Information on Basic Physical and Chemical Properties

<b>Physical States:</b>	<input type="checkbox"/> Gas <input type="checkbox"/> Liquid <input checked="" type="checkbox"/> Solid
<b>Appearance and Odor:</b>	Solid pellets
<b>pH:</b>	13.5
<b>Melting Point:</b>	360.00 C
<b>Boiling Point:</b>	No data.
<b>Flash Pt:</b>	No data.
<b>Evaporation Rate:</b>	No data.
<b>Vapor Pressure (vs. Air or mm Hg):</b>	1 MM_HG at 719.0 C
<b>Vapor Density (vs. Air = 1):</b>	No data.
<b>Specific Gravity (Water = 1):</b>	2.04
<b>Solubility in Water:</b>	No data.
<b>Autoignition Pt:</b>	No data.
<b>Explosive Properties:</b>	No data available.
<b>Oxidizing Properties:</b>	No data available.
<b>9.2 Other Information</b>	
<b>Percent Volatile:</b>	No data.



# SAFETY DATA SHEET

## Potassium Hydroxide

Page: 4

Revision: 10/01/2013  
Supersedes Revision: 01/10/2013

Formula: KOH  
Molecular Weight: 56.10

### Section 10. Stability and Reactivity

- 10.1 Reactivity:** No data available.
- 10.2 Stability:** Unstable [ ] Stable [ X ]
- 10.3 Stability Note(s):** Stable if stored in accordance with information listed on the product insert.
- 10.4 Conditions To Avoid:** absorbs carbon dioxide from air  
do not heat above melting point  
with limited amounts of water violent boiling may occur
- 10.3 Polymerization:** Will occur [ ] Will not occur [ X ]
- 10.5 Incompatibility - Materials To Avoid:** acids  
aluminum  
copper  
flammable liquids  
magnesium  
nitro compounds  
nitromethane  
organic materials  
tin  
trichloroethylene  
zinc
- 10.6 Hazardous Decomposition Or Byproducts:** carbon monoxide  
hydrogen gas  
potassium oxides

### Section 11. Toxicological Information

- 11.1 Information on Toxicological Effects:** The toxicological effects of this product have not been thoroughly studied.
- Potassium Hydroxide - Toxicity Data: Oral LD50 (rat): 273 mg/kg;  
Potassium hydroxide - Irritation Data: Eyes (rabbit): 1 mg (24h) moderate; Skin (human): 50 mg (24h) severe; Skin (rabbit): 50 mg (24h) severe;
- Chronic Toxicological Effects:** Potassium hydroxide - Investigated as a mutagen.  
Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here.  
See actual entry in RTECS for complete information.  
Potassium hydroxide RTECS Number: TT2100000

Hazardous Components (Chemical Name)	CAS #	NTP	IARC	ACGIH	OSHA
1. Potassium hydroxide	1310-58-3	n.a.	n.a.	n.a.	n.a.

### Section 12. Ecological Information

- 12.1 Toxicity:** Avoid release into the environment - harmful to aquatic organisms.  
Runoff from fire control or dilution water may cause pollution.

### Section 13. Disposal Considerations

- 13.1 Waste Disposal Method:** Dispose in accordance with local, state, and federal regulations.

### Section 14. Transport Information

- 14.1 LAND TRANSPORT (US DOT)**
- DOT Proper Shipping Name** Potassium hydroxide, solid
- DOT Hazard Class:** 8



# SAFETY DATA SHEET

## Potassium Hydroxide

Page: 5

Revision: 10/01/2013  
Supersedes Revision: 01/10/2013

DOT Hazard Label: CORROSIVE

UN/NA Number: 1813

Packing Group: II

**14.1 LAND TRANSPORT (European ADR/RID)**

ADR/RID Shipping Name Potassium hydroxide, solid

UN Number: 1813

Hazard Class: 8 - CORROSIVE

Packing Group: II

**14.3 AIR TRANSPORT (ICAO/IATA)**

ICAO/IATA Shipping Name Potassium hydroxide, solid

UN Number: 1813

Hazard Class: 8 - CORROSIVE

Packing Group: II

IATA Classification: 8

**Additional Transport Information:** Transport in accordance with local, state, and federal regulations.  
When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10.  
Therefore packaging does not have to be labeled as Dangerous Goods/Excepted Quantity.

## Section 15. Regulatory Information

**European Community Hazard Symbol codes** C: Corrosive; Xn: Harmful**European Community Risk and Safety Phrases**

- R20/21/22 - Harmful by inhalation, in contact with skin and if swallowed.  
R35 - Causes severe burns.  
S22 - Do not breathe dust.  
S24/25 - Avoid contact with skin and eyes.  
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.  
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label whenever possible.)

**US EPA SARA Title III**

Hazardous Components (Chemical Name)	CAS #	Sec.302 (EHS)	Sec.304 RQ	Sec.313 (TRI)	Sec.110
1. Potassium hydroxide	1310-58-3	No	Yes 1000 LB	No	No

**Other US EPA or State Lists**

Hazardous Components (Chemical Name)	CAS #	CAA HAP,ODC	CWA NPDES	TSCA	CA PROP.65
1. Potassium hydroxide	1310-58-3	No	No	Inventory	No

**Regulatory Information Statement:** This SDS was prepared in accordance with Regulation (EC) No.1272/2008 and European Directive 67/548/EEC as amended.

## Section 16. Other Information

**Revision Date:** 10/01/2013**Company Policy or Disclaimer**

DISCLAIMER: This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.

N.A.=Not available, N.P.=Not applicable, N.D.=Not determined, N.E.=Not established, N.R.=Not required





## SAFETY DATA SHEET

Revision date: 20-Feb-2018

Version: 3.2

Page 1 of 7

### 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

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

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

### 2. HAZARDS IDENTIFICATION

**Classification of the Substance or Mixture**

**GHS - Classification** Not classified as hazardous

**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

## SAFETY DATA SHEET

Material Name: Prevna 13  
Revision date: 20-Feb-2018

Page 2 of 7  
Version: 3.2

## 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.



## SAFETY DATA SHEET

Material Name: Prevnar 13  
Revision date: 20-Feb-2018

Page 3 of 7  
Version: 3.2

**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<sup>3</sup>

**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.)

## SAFETY DATA SHEET

Material Name: Prevnar 13  
Revision date: 20-Feb-2018

Page 4 of 7  
Version: 3.2

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Homogenous Suspension	<b>Color:</b>	White
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Saline suspension</b>			
No data available			
<b>Pneumococcal 13-valent Conjugate</b>			
No data available			
<b>Aluminum phosphate</b>			
No data available			
<b>Succinate buffer</b>			
No data available			
<b>Polysorbate 80</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>	No data available		
<b>Flammability (Solids):</b>	No data available		
<b>Flash Point (Liquid) (°C):</b>	No data available		
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available		
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available		

## 10. STABILITY AND REACTIVITY

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

## SAFETY DATA SHEET

Material Name: Pevnar 13  
Revision date: 20-Feb-2018

Page 5 of 7  
Version: 3.2

**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

## SAFETY DATA SHEET

Material Name: Pevnar 13  
Revision date: 20-Feb-2018

Page 6 of 7  
Version: 3.2

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

**Additional 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

## SAFETY DATA SHEET

Material Name: Prevna 13  
Revision date: 20-Feb-2018

Page 7 of 7  
Version: 3.2

**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

**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



OASIS 146 MULTI-QUAT SANITIZER

## Section 1. Chemical product and company identification

**Product name** : OASIS 146 MULTI-QUAT SANITIZER

**Recommended use and restrictions** : Sanitizer.

Use only for the purpose on the product label.

**Product dilution information** : Up to 4 oz/gal in water

**Supplier's information** : Ecolab Inc. Institutional Division  
370 N. Wabasha Street  
St. Paul, MN 55102  
1-800-352-5326

**Code** : 910787

**Date of issue** : 06 Aug 2013

**EPA Registration No.** : 1677-198

EMERGENCY HEALTH INFORMATION: 1-800-328-0026

Outside United States and Canada CALL 1-651-222-5352 (in USA)

## Section 2. Hazards identification

**GHS Classification** : **Product AS SOLD**  
ACUTE TOXICITY: ORAL - Category 4  
SKIN CORROSION/IRRITATION - Category 1B  
SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 1

### GHS label elements

**Signal word** : Danger

**Symbol** :



**Hazard statements** : Harmful if swallowed.  
Causes severe skin burns and eye damage.

### Precautionary statements

**Prevention** : Wear protective gloves. Wear eye or face protection. Wear protective clothing. Wash hands thoroughly after handling.

**Response** : IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or physician. IF SWALLOWED: Immediately call a POISON CENTER or physician. Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Wash contaminated clothing before reuse. Immediately call a POISON CENTER or physician. IF IN EYES: Rinse cautiously with water for several minutes.

### **Product AT USE DILUTION**

SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2B

Warning

Causes eye irritation.

Wash hands thoroughly after handling.

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

## Section 2. Hazards identification

	Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or physician.	
<b>Storage</b>	: No other specific measures identified.	No other specific measures identified.
<b>Disposal</b>	: See section 13 for waste disposal information.	See section 13 for waste disposal information.
<b>Other hazards</b>	: None known.	None known.

## Section 3. Composition/information on ingredients

**Substance/mixture** : Mixture

### Product AS SOLD

Hazardous ingredients	Concentration Range (%)	CAS number
Alkyl (C14, 50%; C12, 40%; C16, 10%)	3	68424-85-1
Dimethyl benzyl ammonium chloride		
Octyl decyl dimethyl ammonium chloride	2.25	32426-11-2
Didecyl dimethyl ammonium chloride	1.35	7173-51-5
Diocetyl dimethyl ammonium chloride	0.9	5538-94-3
ALCOHOL	1 - 5	64-17-5

### Product AT USE DILUTION

Within the present knowledge of the supplier, this product does not contain any hazardous ingredients in quantities requiring reporting, in accordance with local regulations.

## Section 4. First aid measures

	Product AS SOLD	Product AT USE DILUTION
<b>Eye contact</b>	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation persists.
<b>Skin contact</b>	: Take off immediately all contaminated clothing. Rinse skin with water or shower. Get medical attention immediately. Wash clothing before reuse. Clean shoes thoroughly before reuse.	No known effect after skin contact. Rinse with water for a few minutes.
<b>Inhalation</b>	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately.	No special measures required. Treat symptomatically.
<b>Ingestion</b>	: Get medical attention immediately. Rinse mouth. Do not induce vomiting.	Get medical attention if symptoms occur.
<b>Protection of first-aiders</b>	: 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.	
<b>Notes to physician</b>	: 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.	

See toxicological information (section 11)



## Section 5. Fire-fighting measures

### Product AS SOLD

- Suitable fire extinguishing media** : Use water spray, fog or foam.
- Specific hazards arising from the chemical** : In a fire or if heated, a pressure increase will occur and the container may burst.
- Hazardous thermal decomposition products** : Decomposition products may include the following materials:  
carbon dioxide  
carbon monoxide  
nitrogen oxides  
halogenated compounds
- Specific fire-fighting methods** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6. Accidental release measures

	Product AS SOLD	Product AT USE DILUTION
<b>Personal precautions</b>	: Initiate company's spill response procedures immediately. Keep people out of area. Put on appropriate personal protective equipment (see section 8). Do not touch or walk through spilled material.	Use personal protective equipment as required.
<b>Environmental precautions</b>	: Avoid contact of spilled material and runoff with soil and surface waterways.	Avoid contact of large amounts of spilled material and runoff with soil and surface waterways.
<b>Methods for cleaning up</b>	: Follow company's spill procedures. Keep people away from spill. Put on appropriate personal protective equipment (see section 8). Absorb/neutralize liquid material. Use a tool to scoop up solid or absorbed material and put into appropriate labeled container. Use a tool to scoop up solid or absorbed material and place into appropriate labeled waste container. Use a water rinse for final clean-up.	Use a water rinse for final clean-up.

## Section 7. Handling and storage

	Product AS SOLD	Product AT USE DILUTION
<b>Handling</b>	: Do not ingest. Do not get in eyes or on skin or clothing. Do not breathe vapor or mist. Use only with adequate ventilation. Wash thoroughly after handling.	Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.
<b>Storage</b>	: Keep out of reach of children. Keep container tightly closed.  Store between the following temperatures: 0 and 50°C	Keep out of reach of children. Keep container tightly closed.

## Section 8. Exposure controls/personal protection

### Control parameters

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

	Product AS SOLD	Product AT USE DILUTION
<b>Appropriate engineering controls</b>	: Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. Provide suitable facilities for quick drenching or flushing of the eyes and body in case of contact or splash hazard.	Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
<b>Personal protection</b>		
<b>Eye protection</b>	: Use chemical splash goggles. For continued or severe exposure wear a face shield over the goggles.	No protective equipment is needed under normal use conditions.
<b>Hand protection</b>	: Use chemical-resistant, impervious gloves.	No protective equipment is needed under normal use conditions.
<b>Skin protection</b>	: Use suitable protective equipment.	No protective equipment is needed under normal use conditions.
<b>Respiratory protection</b>	: A respirator is not needed under normal and intended conditions of product use.	A respirator is not needed under normal and intended conditions of product use.
<b>Hygiene measures</b>	: 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.	

## Section 9. Physical and chemical properties

	Product AS SOLD	Product AT USE DILUTION
<b>Physical state</b>	: Liquid.	Liquid.
<b>Color</b>	: Red	Red [Light]
<b>Odor</b>	: disinfectant	disinfectant
<b>pH</b>	: 7.7 (100%)	8.64 [Conc. (% w/w): 100%]
<b>Flash point</b>	: > 100°C	> 100°C
<b>Explosion limits</b>	: Not available.	
<b>Flammability (solid, gas)</b>	: Not available.	
<b>Melting point</b>	: Not available.	
<b>Boiling point</b>	: 100°C (212°F)	
<b>Evaporation rate (butyl acetate = 1)</b>	: Not available.	
<b>Vapor pressure</b>	: Not available.	
<b>Vapor density</b>	: Not available.	

## Section 9. Physical and chemical properties

<b>Relative density</b>	: 0.998 (Water = 1)
<b>Solubility</b>	: Easily soluble in the following materials: cold water and hot water.
<b>Partition coefficient: n-octanol/water</b>	: Not available.
<b>Auto-ignition temperature</b>	: Not available.
<b>Decomposition temperature</b>	: Not available.
<b>Odor threshold</b>	: Not available.
<b>Viscosity</b>	: Not available.

## Section 10. Stability and reactivity

### Product AS SOLD

<b>Stability</b>	: The product is stable.
<b>Possibility of hazardous reactions</b>	: Under normal conditions of storage and use, hazardous reactions will not occur.
<b>Conditions to avoid</b>	: No specific data.
<b>Materials to avoid</b>	: Not available.
<b>Hazardous decomposition products</b>	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## Section 11. Toxicological information

<b>Route of exposure</b>	: Skin contact, Eye contact, Inhalation, Ingestion
--------------------------	--

### Product AS SOLD

#### Symptoms

<b>Eye contact</b>	: Adverse symptoms may include the following: pain watering redness
<b>Skin contact</b>	: Adverse symptoms may include the following: pain or irritation redness blistering may occur
<b>Inhalation</b>	: Adverse symptoms may include the following: coughing Respiratory tract irritation
<b>Ingestion</b>	: Adverse symptoms may include the following: stomach pains

#### Acute toxicity

<b>Eye contact</b>	: Causes serious eye damage.
<b>Skin contact</b>	: Causes severe burns.
<b>Inhalation</b>	: May cause respiratory irritation.
<b>Ingestion</b>	: Harmful if swallowed. May cause burns to mouth, throat and stomach.

#### Toxicity data

##### Product/ingredient name

### Product AT USE DILUTION

Adverse symptoms may include the following: irritation watering redness
No specific data.
No specific data.
No specific data.
Causes eye irritation.
No known significant effects or critical hazards.
No known significant effects or critical hazards.
No known significant effects or critical hazards.

## Section 11. Toxicological information

quaternary ammonium compounds, benzyl- c12-c16-alkyldimethyl, chlorides	LD50 Dermal	Rabbit	3340 mg/kg
	LD50 Oral	Rat	344 mg/kg
1-decanaminium, n,n-dimethyl-n-octyl-, chloride	LC50 Inhalation Dusts and mists	Rat	0.07 mg/l
	LD50 Dermal	Rabbit	2930 mg/kg
	LD50 Oral	Rat	238 mg/kg
ethanol	LC50 Inhalation Vapor	Rat	117 mg/l
	LD50 Dermal	Rabbit	15800 mg/kg
	LD50 Oral	Rat	10470 mg/kg
didecyldimethylammonium chloride	LC50 Inhalation Dusts and mists	Rat	0.07 mg/l
	LD50 Dermal	Rabbit	2930 mg/kg
	LD50 Oral	Rat	1150 mg/kg

### Chronic toxicity

<b>Carcinogenicity</b>	: No known significant effects or critical hazards.
<b>Mutagenicity</b>	: No known significant effects or critical hazards.
<b>Teratogenicity</b>	: No known significant effects or critical hazards.
<b>Developmental effects</b>	: No known significant effects or critical hazards.
<b>Fertility effects</b>	: No known significant effects or critical hazards.

## Section 12. Ecological information

### Product AS SOLD

**Ecotoxicity** : This material is toxic to aquatic life.

### Aquatic and terrestrial toxicity

Product/ingredient name	Result	Species	Exposure
Not available.			

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

## Section 13. Disposal considerations

**Disposal methods** : **Product AS SOLD**  
: Avoid disposal. Attempt to use product completely in accordance with intended use. Disposal should be in accordance with applicable regional, national and local laws and regulations.

### Product AT USE DILUTION

Diluted product can be flushed to sanitary sewer. Discard empty container in trash.

## Section 14. Transport information

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

### DOT

**DOT Classification** : Not regulated.

### IMO/IMDG

**IMO/IMDG Classification** : Not regulated.

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

### Product AT USE DILUTION

Not intended for transport.

## Section 15. Regulatory information

Product AS SOLD

### U.S. Federal regulations

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

EPA Registration No. : 1677-198

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

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

### SARA 313

### Product name

### CAS number

### Concentration

Form R - Reporting requirements : No listed substance

California Prop. 65 : No listed substance

## Section 16. Other information

Product AS SOLD

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

Health	*	3
Flammability		0
Physical hazards		0

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



Date of issue : 06 Aug 2013

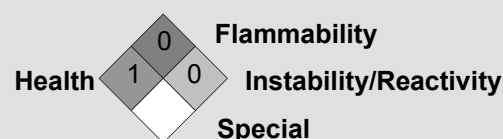
Prepared by : Regulatory Affairs  
1-800-352-5326

### Notice to reader

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

Product AT USE DILUTION

Health		1
Flammability		0
Physical hazards		0





Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

# SAFETY DATA SHEET

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



HEALTH • HYGIENE • HOME

## 1. Product and company identification

**Product name** : Professional Lysol® Brand III Kills 99.9% of Viruses & Bacteria\*\* Disinfectant Spray, All Scents

**Distributed by** : Reckitt Benckiser LLC.  
Morris Corporate Center IV  
399 Interpace Parkway (P.O. Box 225)  
Parsippany, New Jersey 07054-0225  
+1 973 404 2600

**Emergency telephone number (Medical)** : 1-800-338-6167

**Emergency telephone number (Transport)** : 1-800-424-9300 (U.S. & Canada) CHEMTREC  
Outside U.S. and Canada (North America), call Chemtrec:703-527-3887

**Website:** : <http://www.rbnainfo.com>

**Product use** : Disinfectant.

This SDS is designed for workplace employees, emergency personnel and for other conditions and situations where there is greater potential for large-scale or prolonged exposure, in accordance with the requirements of USDOL Occupational Safety and Health Administration.

This SDS is not applicable for consumer use of our products. For consumer use, all precautionary and first aid language is provided on the product label in accordance with the applicable government regulations, and shown in Section 15 of this SDS.

**SDS #** : D0224478 v5.0

**Formulation #:** : 1338-022 (0175933) Original  
1544-106 (0175940) Fresh  
1338-019 (0175919) Country  
1178-172 (0175917) Crisp Linen / Crystal Waters  
1338-015 (0175918) Spring Waterfall  
1338-026 (0175929) Early Morning Breeze / Lavender

**EPA ID No.** : 777-99-675

**UPC Code / Sizes** : 19 oz. Aerosol Cans  
Original Scent, 36241-04650  
Fresh, 36241-04675  
Country Scent®, 36241-74276  
Crisp Linen®, 36241-74828  
Spring Waterfall®, 36241-76075  
Crystal Waters, 36241-84044  
Early Morning Breeze, 36241-81737  
Lavender, 36241-89097

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

## 2. Hazards identification

**Classification of the substance or mixture** : FLAMMABLE AEROSOLS - Category 2

### GHS label elements

**Hazard pictograms** :



**Signal word** : Warning

**Hazard statements** : Flammable aerosol.  
Pressurized container: may burst if heated.

### Precautionary statements

**General** : Keep out of reach of children. If medical advice is needed, have product container or label at hand.

**Prevention** : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Pressurized container: Do not pierce or burn, even after use. Do not spray on an open flame or other ignition source.

**Response** : Not applicable.

**Storage** : Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

**Disposal** : Not applicable.

**Supplemental label elements** : None known.

**Hazards not otherwise classified** : None known.

## 3. Composition/information on ingredients

**Substance/mixture** : Mixture

Ingredient name	%	CAS number
Ethyl alcohol	30 - 60	64-17-5
butane	1 - 5	106-97-8
propane	< 2.5	74-98-6

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

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

## 4. First aid measures

### Description of necessary first aid measures

**Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.



Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

## 4. First aid measures

- |                     |   |
|---------------------|---|
| <b>Inhalation</b>   | : 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.  |
| <b>Skin contact</b> | : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.   |
| <b>Ingestion</b>    | : 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

- |                     |   |
|---------------------|---|
| <b>Eye contact</b>  | : May cause eye irritation upon direct contact with eyes. |
| <b>Inhalation</b>   | : No known significant effects or critical hazards.       |
| <b>Skin contact</b> | : No known significant effects or critical hazards.       |
| <b>Ingestion</b>    | : No known significant effects or critical hazards.       |

#### Over-exposure signs/symptoms

- |                     |   |
|---------------------|---|
| <b>Eye contact</b>  | : Adverse symptoms may include the following:<br>irritation<br>redness                    |
| <b>Inhalation</b>   | : Adverse symptoms may include the following:<br>respiratory tract irritation<br>coughing |
| <b>Skin contact</b> | : No specific data.   |
| <b>Ingestion</b>    | : No specific data.   |

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

- |                                   |  |
|-----------------------------------|--|
| <b>Notes to physician</b>         | : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.  |
| <b>Specific treatments</b>        | : No specific treatment.   |
| <b>Protection of first-aiders</b> | : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. |

See toxicological information (Section 11)

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

## 5. Fire-fighting measures

### Extinguishing media

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

**Unsuitable extinguishing media** : None known.

**Specific hazards arising from the chemical** : Flammable aerosol. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion. Gas may accumulate in low or confined areas or travel a considerable distance to a source of ignition and flash back, causing fire or explosion. Bursting aerosol containers may be propelled from a fire at high speed. Runoff to sewer may create fire or explosion hazard.

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

**Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

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

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. In the case of aerosols being ruptured, care should be taken due to the rapid escape of the pressurized contents and propellant. If a large number of containers are ruptured, treat as a bulk material spillage according to the instructions in the clean-up section. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

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

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

### Methods and materials for containment and cleaning up

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

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

## 6. Accidental release measures

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

## 7. Handling and storage

### Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing gas. Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Empty containers retain product residue and can be hazardous.

- Conditions for safe storage, including any incompatibilities** : Do not store above the following temperature: 50°C (122°F). Store in accordance with local regulations. Store away from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Use appropriate containment to avoid environmental contamination.

## 8. Exposure controls/personal protection

### Control

#### Occupational exposure limits

Ingredient name	Exposure limits
Ethyl alcohol	<b>ACGIH TLV (United States, 6/2013).</b> STEL: 1000 ppm 15 minutes. <b>OSHA PEL 1989 (United States, 3/1989).</b> TWA: 1000 ppm 8 hours. TWA: 1900 mg/m <sup>3</sup> 8 hours. <b>NIOSH REL (United States, 10/2013).</b> TWA: 1000 ppm 10 hours. TWA: 1900 mg/m <sup>3</sup> 10 hours. <b>OSHA PEL (United States, 2/2013).</b> TWA: 1000 ppm 8 hours. TWA: 1900 mg/m <sup>3</sup> 8 hours.
butane	<b>OSHA PEL 1989 (United States, 3/1989).</b> TWA: 800 ppm 8 hours. TWA: 1900 mg/m <sup>3</sup> 8 hours. <b>NIOSH REL (United States, 10/2013).</b> TWA: 800 ppm 10 hours. TWA: 1900 mg/m <sup>3</sup> 10 hours. <b>ACGIH TLV (United States, 6/2013).</b> STEL: 1000 ppm 15 minutes.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

## 8. Exposure controls/personal protection

propane

**OSHA PEL 1989 (United States, 3/1989).**

TWA: 1000 ppm 8 hours.

TWA: 1800 mg/m<sup>3</sup> 8 hours.**NIOSH REL (United States, 10/2013).**

TWA: 1000 ppm 10 hours.

TWA: 1800 mg/m<sup>3</sup> 10 hours.**OSHA PEL (United States, 2/2013).**

TWA: 1000 ppm 8 hours.

TWA: 1800 mg/m<sup>3</sup> 8 hours.

- Appropriate engineering controls** : Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.
- Individual protection measures**
- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. When there is a risk of ignition from static electricity, wear anti-static protective clothing. For the greatest protection from static discharges, clothing should include anti-static overalls, boots and gloves.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

## 9. Physical and chemical properties

### Appearance

Physical state : Liquid. [Aerosol.]

Color : Clear.

Odor : Characteristic.

Odor threshold : Not available.

pH : 10.8 to 11.8 [Conc. (% w/w): 100%]

Melting point : Not available.

Boiling point : Not available.

Flash point : Closed cup: 25.6°C (78.1°F)

Evaporation rate : Not available.

Flammability (solid, gas) : Not available.

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

Vapor pressure : Not available.

Vapor density : Not available.

Relative density : 0.8667 to 0.8967 g/cm<sup>3</sup> [20 to 25°C]

Solubility : Easily soluble in the following materials: cold water and hot water.

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

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : Not available.

### Aerosol product

Type of aerosol : Spray

Heat of combustion : 17.99 kJ/g

Ignition distance : &lt;45.72 cm

## 10. Stability and reactivity

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

Chemical stability : The product is stable.

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

Conditions to avoid : Avoid all possible sources of ignition (spark or flame).

Incompatible materials : Do not mix with household chemicals.

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

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

## 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Ethyl alcohol	LC50 Inhalation Vapor	Rat	124700 mg/m <sup>3</sup>	4 hours
	LD50 Oral	Rat	7 g/kg	-
*Professional Lysol® Disinfectant Spray, All Scents (Aerosol)	LC50 Inhalation Vapor	Rat	>2.12 mg/l	4 hours Maximum attainable concentration

**Conclusion/Summary** : Not classified Harmful. \*Information is based on toxicity test result of the concentrate of a similar product.

#### Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Ethyl alcohol	Eyes - Moderate irritant	Rabbit	-	0.066666667 minutes 100 milligrams	-
	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
	Eyes - Moderate irritant	Rabbit	-	100 microliters	-
	Eyes - Severe irritant	Rabbit	-	500 milligrams	-
	Skin - Mild irritant	Rabbit	-	400 milligrams	-
	Skin - Moderate irritant	Rabbit	-	24 hours 20 milligrams	-
*Professional Lysol® Disinfectant Spray, All Scents (Aerosol)	Eyes - Cornea opacity	Rabbit	< 1	72 hours	4 days
	Skin - Primary dermal irritation index (PDII)	Rabbit	0.3	4 hours	72 hours

#### Conclusion/Summary

**Skin** : Slightly irritating to the skin. \*Information is based on toxicity test result of the concentrate of a similar product.

**Eyes** : Moderately irritating to eyes. \*Information is based on toxicity test result of the concentrate of a similar product.

#### Sensitization

Not available.

#### Mutagenicity

Not available.

#### Carcinogenicity

Not available.

#### Classification

Product/ingredient name	OSHA	IARC	NTP
Ethyl alcohol	-	1	-

#### Reproductive toxicity

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

## 11. Toxicological information

Not available.

### Teratogenicity

Not available.

### Specific target organ toxicity (single exposure)

Not available.

### Specific target organ toxicity (repeated exposure)

Not available.

### Aspiration hazard

Not available.

**Information on the likely routes of exposure** : Not available.

### Potential acute health effects

**Eye contact** : May cause eye irritation upon direct contact with eyes.  
**Inhalation** : No known significant effects or critical hazards.  
**Skin contact** : No known significant effects or critical hazards.  
**Ingestion** : No known significant effects or critical hazards.

### Symptoms related to the physical, chemical and toxicological characteristics

**Eye contact** : Adverse symptoms may include the following:  
 irritation  
 redness  
**Inhalation** : Adverse symptoms may include the following:  
 respiratory tract irritation  
 coughing  
**Skin contact** : No specific data.  
**Ingestion** : No specific data.

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

#### Short term exposure

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

#### Long term exposure

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

### Potential chronic health effects

Not available.

**General** : No known significant effects or critical hazards.  
**Carcinogenicity** : No known significant effects or critical hazards.  
**Mutagenicity** : No known significant effects or critical hazards.  
**Teratogenicity** : No known significant effects or critical hazards.

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

## 11. Toxicological information

**Developmental effects** : No known significant effects or critical hazards.  
**Fertility effects** : No known significant effects or critical hazards.

### Numerical measures of toxicity

#### Acute toxicity estimates

Not available.

## 12. Ecological information

### Toxicity

Product/ingredient name	Result	Species	Exposure
Ethyl alcohol	Acute EC50 17.921 mg/l Marine water	Algae - Ulva pertusa	96 hours
	Acute EC50 2000 µg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 25500 µg/l Marine water	Crustaceans - Artemia franciscana - Larvae	48 hours
	Acute LC50 42000 µg/l Fresh water	Fish - Oncorhynchus mykiss	4 days
	Chronic NOEC 4.995 mg/l Marine water	Algae - Ulva pertusa	96 hours
	Chronic NOEC 0.375 ul/L Fresh water	Fish - Gambusia holbrooki - Larvae	12 weeks

### Persistence and degradability

Not available.

### Bioaccumulative potential

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
Ethyl alcohol	-0.35	-	low

### Mobility in soil

**Soil/water partition coefficient (K<sub>oc</sub>)** : Not available.

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

## 13. Disposal considerations

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

**Code #** : D0224478\_US  
Professional

**SDS #** : D0224478 v5.0

**Date of issue** : 26/06/2015.

**10/14**








Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

### 13. Disposal considerations

### 14. Transport information

Regulatory information	UN number	Proper shipping name	Classes	PG*	Label	Additional information
<b>DOT Classification</b>	UN1950	Aerosols, flammable	2.1	-		Limited quantity
<b>TDG Classification</b>	UN1950	Aerosols, flammable	2.1	-		Limited quantity
<b>Mexico Classification</b>	UN1950	AEROSOL	2.1	-		Limited quantity
<b>IMDG Class</b>	UN1950	Aerosols, flammable	2.1	-		Limited quantity
<b>IATA-DGR Class</b>	UN1950	Aerosols, flammable	2.1	-		See DG List

PG\* : Packing group

### 15. Regulatory information

**U.S. Federal regulations** : TSCA 8(a) PAIR: 2-methylpropan-2-ol  
TSCA 8(a) CDR Exempt/Partial exemption: Not determined  
United States inventory (TSCA 8b): All components are listed or exempted.  
Clean Water Act (CWA) 311: ammonia  
Clean Air Act (CAA) 112 regulated flammable substances: butane; propane

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

Clean Air Act Section 602 Class I Substances

: Not listed

Clean Air Act Section 602 Class II Substances

: Not listed

DEA List I Chemicals (Precursor Chemicals)

: Not listed

DEA List II Chemicals (Essential Chemicals)

: Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

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D0224478 v5.0

## 15. Regulatory information

SARA 304 RQ : Not applicable.

## SARA 311/312

Classification : Fire hazard

## Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Ethyl alcohol	30 - 60	Yes.	No.	No.	Yes.	No.

## State regulations

Massachusetts : The following components are listed: ETHYL ALCOHOL; BUTANE; PROPANE

New York : None of the components are listed.

New Jersey : The following components are listed: ETHYL ALCOHOL; ALCOHOL; BUTANE; PROPANE

Pennsylvania : The following components are listed: DENATURED ALCOHOL; BUTANE; PROPANE

## Label elements

Signal word: : CAUTION

Hazard statements : Causes moderate eye irritation

Precautionary measures : Do not get in eyes, on skin or on clothing. Wash thoroughly after handling. Wash with soap and water.

Keep out of the reach of children.

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

Hazard statements :



Flammable

## 16. Other information

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

Health	1
Flammability	3
Physical hazards	0
Personal protection	B

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings are not required on MSDSs under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

Code # : D0224478\_US  
Professional

SDS # : D0224478 v5.0

Date of issue : 26/06/2015.

12/14

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

## 16. Other information

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



NFPA (30B) aerosol Flammability Level 1

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

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

**Date of issue** : 26/06/2015.  
**Date of previous issue** : 09/04/2015.  
**Version** : 5  
**Prepared by** : Reckitt Benckiser LLC.  
Product Safety Department  
1 Philips Parkway  
Montvale, New Jersey 07646-1810 USA.  
FAX: 201-476-7770

**Revision comments** : Revision as per US GHS. Correction to NFPA 30B level.

Indicates information that has changed from previously issued version.

### Notice to reader

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

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

Conforms to USDOL OSHA 29CFR 1910.1200 HAZCOM

D0224478 v5.0

## 16. Other information



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



Revision Number: 6

# Prolia<sup>®</sup>

## Safety Data Sheet

Date Issued 01-Feb-2013

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

#### 1.1 Product identifier

**Product Name:** Prolia  
**Common Name:** Denosumab  
**Chemical Name:** Not Applicable  
**Synonyms:** AMG 162, desnoumab

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

**Recommended Use:** Pharmaceutical  
**Uses advised against:** No information available

#### Manufacturer:

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

#### Emergency Telephone Number:

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

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

Pharmaceutical product intended for clinical and manufacturing purposes only. Product contains denosumab, an active pharmaceutical ingredient for the treatment of bone diseases characterized by excessive bone resorption, including those from cancer-related bone destruction; treatment-related bone loss; and pathologic bone loss. The pharmacologic action of Prolia<sup>®</sup> appears to be reversible. Avoid inhalation, skin contact, eye contact, and accidental ingestion. Does not meet GHS classification criteria and therefore is not classified.

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

Not classified

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

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

#### 2.2 Label elements

Not classified

#### 2.3 Other Hazards

No information available



Revision Number: 6

# Prolia<sup>®</sup> Safety Data Sheet

Date Issued 01-Feb-2013

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

**Ingredients:** Proprietary information

**Chemical Name:** Not Applicable

**CAS-No:** 615258-40-7

**Each 1 mL single-use vial of Prolia<sup>®</sup> contains 60 mg denosumab (60mg/mL solution) and the following:**

	CAS Number:	Amount
Sorbitol	50-70-4	4.7 %
Sodium acetate	127-09-3	17 mM
Water for Injection, USP	7732-18-5	---

**Each 1 mL single-use prefilled syringe of Prolia<sup>®</sup> contains 60 mg denosumab (60mg/mL solution) and the following:**

	CAS Number:	Amount
Sorbitol	50-70-4	4.7 %
Sodium acetate	127-09-3	17 mM
Water for Injection, USP	7732-18-5	---

## 4. FIRST AID MEASURES

### 4.1 Description of first-aid measures

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

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

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

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

**Notes to Physician:** Treat symptomatically.



Revision Number: 6

# Prolia<sup>®</sup> Safety Data Sheet

Date Issued 01-Feb-2013

## 5. FIRE-FIGHTING MEASURES

### 5.1 Extinguishing media

**Flammable Properties:** Not applicable/aqueous solution.

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

### 5.2 Special hazards arising from the substance or mixture

**Hazardous Combustion Products:** None

### 5.3 Advice for firefighters

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

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

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

## 7. HANDLING AND STORAGE

### 7.1 Precautions for Safe Handling

**Handling and Storage:** Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment thoroughly after each use. Store in a well ventilated area.



Revision Number: 6

## Prolia<sup>®</sup> Safety Data Sheet

Date Issued 01-Feb-2013

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

**Occupational Exposure Limit:** No exposure guidelines established by ACGIH, NIOSH or OSHA. Amgen recommends an occupational exposure limit (OEL) of 60 µg/m<sup>3</sup> as an 8-hour time weighted average over a 40-hour work week. The OEL is designed as an acceptable airborne concentration of a substance for which it is believed that workers may be repeatedly exposed day after day without adverse health effects. Prolia<sup>®</sup> has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 3 compound (20 µg/m<sup>3</sup> - 100 µg/m<sup>3</sup>).

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

#### 8.2 Exposure controls

##### Personal Protective Equipment

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

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

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

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

#### 8.3 Environmental exposure controls

**Environmental Exposure Controls** Avoid release to the environment.





Revision Number: 6

# Prolia<sup>®</sup> Safety Data Sheet

Date Issued 01-Feb-2013

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear colorless to slightly yellow
<b>Physical State:</b>	Liquid
<b>Molecular Weight:</b>	147kD
<b>Odor:</b>	No information available
<b>Odor Threshold:</b>	No information available
<b>pH:</b>	5.2
<b>Melting Point:</b>	Not applicable
<b>Flash Point:</b>	Not applicable
<b>Evaporation Rate:</b>	No information available
<b>Lower explosive limit:</b>	No information available
<b>Upper explosive limit:</b>	No information available
<b>Vapor Pressure:</b>	No information available
<b>Vapor Density (air = 1):</b>	No information available
<b>Relative density:</b>	No information available
<b>Water Solubility:</b>	Not applicable
<b>Partition Coefficient (log Kow):</b>	No information available
<b>Viscosity:</b>	No information available

## 10. STABILITY AND REACTIVITY

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



Revision Number: 6

## Prolia<sup>®</sup> Safety Data Sheet

Date Issued 01-Feb-2013

### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

<b>Acute Toxicity:</b>	No information available
<b>Skin corrosion/irritation:</b>	No information available
<b>Serious eye damage/eye irritation:</b>	No information available
<b>Respiratory or skin sensitization:</b>	No information available
<b>Germ cell mutagenicity:</b>	No information available
<b>Carcinogenicity:</b>	No information available
<b>Reproductive toxicity:</b>	Even though this does not meet GHS classification, the following data is available: Prolia <sup>®</sup> exposure in cynomolgus monkeys by subcutaneous injection at 50 mg/kg from gestation day 20 to parturition resulted in increased fetal loss, stillbirths, and postnatal mortality, along with histological changes in infants. In general, the effects observed in mothers and infants were consistent with the pharmacological action of denosumab as a monoclonal antibody against RANKL and an inhibitor of osteoclastic bone resorption. No effects on male or female fertility have been observed.
<b>STOT - single exposure:</b>	No information available
<b>STOT - repeated exposure:</b>	Even though this does not meet GHS classification, the following data is available: Prolia <sup>®</sup> was administered to cynomolgus monkeys via subcutaneous injection once monthly for 1 year at doses of 1, 10 and 50 mg/kg and no adverse effects were observed. Denosumab produced rapid and sustained decreases in markers of bone turnover and increases in bone mineral density at doses >1 mg/kg, which were attributable to the pharmacologic activity of the monoclonal antibody.
<b>Aspiration Hazard:</b>	No information available



Revision Number: 6

## Prolia<sup>®</sup> Safety Data Sheet

Date Issued 01-Feb-2013

### 12. ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Ecotoxicity effects: No information available

#### 12.2 Persistence and degradability

Persistence/Degradability: No information available

#### 12.3 Bioaccumulative potential

Bioaccumulation/ Accumulation: No information available

#### 12.4 Mobility in soil

Mobility in Environmental Media: No information available

#### 12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment: No information available

#### 12.6 Other adverse effects

Other Adverse Effects: No information available

### 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

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

### 14. TRANSPORT INFORMATION

DOT Not regulated by U.S. DOT or IATA



Revision Number: 6

## Prolia<sup>®</sup> Safety Data Sheet

Date Issued 01-Feb-2013

### 15. REGULATORY INFORMATION

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

##### International Inventories

<b>TSCA:</b>	-
<b>EINECS/ELINCS</b>	-
<b>DSL/NDSL</b>	-
<b>PICCS:</b>	-
<b>ENCS:</b>	-
<b>CHINA:</b>	-
<b>AICS:</b>	-
<b>KECL:</b>	-

##### Legend

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

##### State Regulations

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

#### 15.2 Chemical safety assessment

No CSA has been conducted.



Revision Number: 6

## **Prolia<sup>®</sup>** **Safety Data Sheet**

Date Issued 01-Feb-2013

### **16. OTHER INFORMATION**

#### **Text of R phrases mentioned in Section 2**

No information available

**Revision Number:** 6

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections, which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it may be biologically active.



Conforms to HazCom 2012/United States

# SAFETY DATA SHEET

**Promethazine HCl Injection, USP****hikma.**

## Section 1. Identification

<b>GHS product identifier</b>	: Promethazine HCl Injection, USP
<b>Synonyms</b>	: Phenergan® (Promethazine HCl) Injection
<b>Product code</b>	: Not available.
<b>Chemical family</b>	: Anticholinergic Agent. Antihistaminic Agent. Antiemetic. Sedative.
<b>Product type</b>	: Regulated prescription drug.
<b>Container information</b>	: 1 mL vials or ampuls.
<b>Identified uses</b>	: Pharmaceutical.
<b>Supplier's details</b>	: Hikma Pharmaceuticals USA Inc. 246 Industrial Way West Eatontown, New Jersey (NJ) 07724
<b>Emergency telephone number (with hours of operation)</b>	: CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887 24/7

## Section 2. Hazards identification

<b>OSHA/HCS status</b>	: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
<b>Classification of the substance or mixture</b>	: 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.

<b>Ingredient name</b>	<b>%</b>	<b>CAS number</b>
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

<b>Flammability (solid, gas)</b>	: Not available.
<b>Lower and upper explosive (flammable) limits</b>	: Not available.
<b>Vapor pressure</b>	: Not available.
<b>Vapor density</b>	: Not available.
<b>Relative density</b>	: Not available.
<b>Solubility</b>	: Not available.
<b>Partition coefficient: n-octanol/water</b>	: Not available.
<b>Auto-ignition temperature</b>	: Not available.
<b>Decomposition temperature</b>	: Not available.
<b>Viscosity</b>	: Not available.

## Section 10. Stability and reactivity

<b>Reactivity</b>	: No specific test data related to reactivity available for this product or its ingredients.
<b>Chemical stability</b>	: The product is stable.
<b>Possibility of hazardous reactions</b>	: Under normal conditions of storage and use, hazardous reactions will not occur.
<b>Conditions to avoid</b>	: No specific data.
<b>Incompatible materials</b>	: Reactive or incompatible with the following materials: oxidizing materials, acids and alkalis.
<b>Hazardous decomposition products</b>	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

There is no data available.

#### Irritation/Corrosion

There is no data available.

#### Sensitization

There is no data available.

#### Carcinogenicity

There is no data available.

#### Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Promethazine hydrochloride	Category 3	Not applicable.	Respiratory tract irritation

#### Specific target organ toxicity (repeated exposure)

There is no data available.

#### Aspiration hazard

There is no data available.

## Section 11. Toxicological information

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

### Potential acute health effects

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

### Symptoms related to the physical, chemical and toxicological characteristics

**Eye contact** : No known significant effects or critical hazards.  
**Inhalation** : No known significant effects or critical hazards.  
**Skin contact** : Adverse symptoms may include the following:  
 irritation  
 redness  
**Ingestion** : No known significant effects or critical hazards.

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

#### Short term exposure

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

#### Long term exposure

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

### Potential chronic health effects

**General** : Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.  
**Carcinogenicity** : No known significant effects or critical hazards.  
**Mutagenicity** : No known significant effects or critical hazards.  
**Teratogenicity** : No known significant effects or critical hazards.  
**Developmental effects** : No known significant effects or critical hazards.  
**Fertility effects** : No known significant effects or critical hazards.

### Numerical measures of toxicity

#### Acute toxicity estimates

Route	ATE value
Oral	13333.3 mg/kg
Inhalation (vapors)	293.3 mg/L

## Section 12. Ecological information

### Toxicity

There is no data available.

### Persistence and degradability

There is no data available.

### Bioaccumulative potential

There is no data available.

### Mobility in soil

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

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

## Section 13. Disposal considerations

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

## Section 14. Transport information

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

**AERG** : Not applicable.

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



Promethazine HCl Injection, USP

## Section 14. Transport information

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

## Section 15. Regulatory information

**U.S. Federal regulations** : TSCA 8(a) PAIR: Sodium Metabisulphite  
TSCA 8(a) CDR Exempt/Partial exemption: Not determined  
United States inventory (TSCA 8b): All components are listed or exempted.  
Clean Water Act (CWA) 307: Phenol  
Clean Water Act (CWA) 311: Phenol

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

Clean Air Act Section 602 : Not listed  
Class I Substances

Clean Air Act Section 602 : Not listed  
Class II Substances

DEA List I Chemicals : Not listed  
(Precursor Chemicals)

DEA List II Chemicals : Not listed  
(Essential Chemicals)

### SARA 302/304

#### Composition/information on ingredients

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
Phenol	0.1 - 1	Yes.	-	-	-	-

SARA 304 RQ : Not applicable.

### SARA 311/312

#### Composition/information on ingredients

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

### State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

### California Prop. 65

No products were found.

### International regulations

## Section 15. Regulatory information

<b>International lists</b>	: <b>Australia inventory (AICS):</b> All components are listed or exempted. <b>China inventory (IECSC):</b> Not determined. <b>Japan inventory:</b> All components are listed or exempted. <b>Korea inventory:</b> All components are listed or exempted. <b>Malaysia Inventory (EHS Register):</b> Not determined. <b>New Zealand Inventory of Chemicals (NZIoC):</b> All components are listed or exempted. <b>Philippines inventory (PICCS):</b> Not determined. <b>Taiwan inventory (CSNN):</b> Not determined.
<b>Chemical Weapons Convention List Schedule I Chemicals</b>	: Not listed
<b>Chemical Weapons Convention List Schedule II Chemicals</b>	: Not listed
<b>Chemical Weapons Convention List Schedule III Chemicals</b>	: Not listed

## Section 16. Other information

### History

<b>Revision date mm/dd/yyyy</b>	: 12/15/2018
<b>Version</b>	: 2
<b>Prepared by</b>	: KMK Regulatory Services Inc.
<b>Key to abbreviations</b>	: 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.





## QuickVue® iFOB TEST



Catalog No.: 20194/20196/20201/20204/20205  
Reference No.: K021423

Revision Date: August 27, 2007

### SECTION 1 – Kit / Preparation and Company Identification

- 1.1 QUICKVue iFOB TEST** *(For in vitro diagnostic use only)*
- 1.2** The QuickVue iFOB (immunochemical Fecal Occult Blood) test is an immunochemical device intended for the qualitative detection of fecal occult blood by laboratories or physicians' offices.
- 1.3 Manufacturer:** Quidel Corporation – 10165 McKellar Court – San Diego, CA 92121  
**Telephone No.:** 1-858-552-1100 **Toll Free No.:** 1-800-874-1517 **Fax No.:** 1-858-453-4338
- 1.4 Emergency No.:** Poison Control @ 1-800-876-4766 (USA only)

### SECTION 2 – Composition / Ingredients Information

- 2.1 Description of Components:** Test cassettes, specimen collection tube with 2 mL FOB Buffer, specimen collection paper, specimen pouch, absorbent sleeve and return mail pouch.

**NOTE:** Variations of the kits purchased may include all of these components or only individual components.

- 2.2 Hazardous Ingredients:** Dangerous solid or liquid substances present in >1% (or as required by applicable U.S., Canadian and E.U. regulations):

**\*\*No hazardous components in excess of 1% are contained within this kit.**

CAS#	EINECS	Chemical Name	Kit Component	% Weight	Classification:			
					US OSHA	WHMIS	EU	Risk Phrases
26628-22-8	247-852-1	Sodium Azide	Specimen Collection Tube FOB Buffer	<0.02	N/A	N/A	-	None

\*\*See Section 15 and Section 16 for additional information on hazard classifications.

### SECTION 3 – Hazard Identification

**Emergency Overview:** As part of good industrial and personal hygiene and safety procedure, avoid all unnecessary exposure to the chemical components within this kit and ensure prompt removal from skin, eyes, and clothing.

- 3.1** No components within this kit are considered as hazardous or dangerous preparations as defined by the Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), and/or the European Union (EU) Directives 1999/45/EC and 67/548/EEC. **Significant health effects are NOT anticipated from routine use when adhering to the instructions listed in the Package Insert provided with assay kit.**
- 3.2** Contact with the **FOB Buffer** solution to the eyes and/or skin may cause slight irritation upon prolonged exposure. Avoid prolonged contact with any chemical within this kit.
- 3.3** This kit may contain material of human or animal origin and should be considered as potentially capable of transmitting infectious diseases.
- 3.4** All patient samples should be handled as potentially infectious. Follow **Universal Precautions** as necessary.
- 3.5 Warning Properties:**

Chemical Name	Kit Component	Degree	Description
Sodium Azide <0.02%	Specimen Collection Tube	Poor	Clear odorless solution



## QuickVue® iFOB TEST



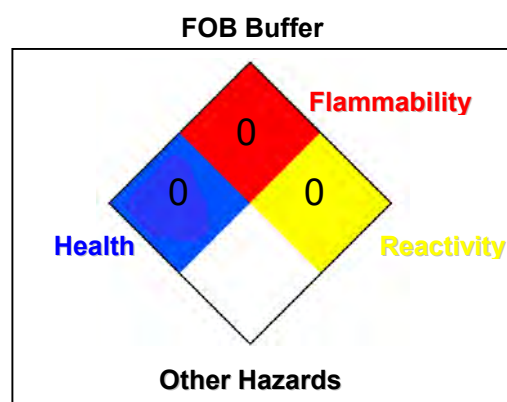
### SECTION 4 – First Aid Measures

#### Special Instructions:

- 4.1 Inhalation** *Inhalation of any component in this kit is unlikely.* If a component of this kit is inhaled and causes discomfort, move exposed individual to fresh air. Seek medical attention if breathing is difficult or symptoms persist.
- 4.2 Eye Contact** FOB Buffer may cause slight irritation upon contact. In case of contact with eyes, immediately wash eyes under potable running water for at least 15 minutes, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.
- 4.3 Skin Contact** FOB Buffer may cause slight irritation upon contact. Remove any contaminated clothing and wash affected area with plenty of soap and water. If pain or irritation occurs, obtain medical attention.
- 4.4 Ingestion** If FOB Buffer is swallowed, wash mouth out with water provided person is conscious. If irritation or discomfort occurs, obtain medical attention.

### SECTION 5 – Fire Fighting Measures

- 5.1 Extinguishing Media:** For small fires, use dry chemical, carbon dioxide, or alcohol-resistant foam.
- 5.2 Special Fire Fighting Procedures:** This material will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the surrounding fire. Utilize proper personal protective equipment when responding to any fire. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.
- 5.3 Unusual Fire and Explosion Hazards:** When involved in a fire, this material can decompose and produce irritating fumes and toxic gases (e.g., Carbon monoxide, Carbon dioxide).
- Explosion Sensitivity to Mechanical Impact: Not sensitive under normal conditions.
- Explosion Sensitivity to Static Discharge: Not sensitive under normal conditions.
- 5.4 Additional Considerations (FOB Buffer):**
- |       |                               |                 |
|-------|-------------------------------|-----------------|
| 5.4.1 | Flash Point                   | Non Combustible |
| 5.4.2 | Auto-ignition Temperature     | Not Applicable  |
| 5.4.3 | Upper / Lower Explosion Limit | Not Applicable  |
- 5.5 NFPA Ratings (see Section 16 for definitions of numerical ratings):**



Reference only

**\*\*** Only trained and competent personnel shall attempt to extinguish a fire. Contact emergency response personnel as required. Be cautious of surrounding materials that may react with the extinguishing media.



## QuickVue® iFOB TEST



### SECTION 6 – Accidental Release Measures

- 6.1 Personal Precautions:** This kit contains materials of biological origin. Avoid personal contact. Use Universal Precautions during clean-up procedures.
- 6.2 Environmental Precautions:** No environmental hazard is anticipated provided that the material is handled and disposed of with due care. Contain spill to prevent migration.
- 6.3 Spill and Leak Procedures:** Large spills of this kit are unlikely. Personnel who have received basic chemical safety training can generally handle small-scale releases, such as 1 container in this kit. Utilize safety glasses, nitrile gloves, and lab coat/apron when responding to spills involving the components of this kit. Absorb liquid and place in container suitable for disposal. Dispose of in accordance with applicable U.S. Federal, State, or local procedures or appropriate standards of Canada or the EU (see Section 13, Disposal Considerations).

### SECTION 7 – Handling and Storage

- 7.1 Handling:** As with all chemicals, avoid getting components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. This kit should be handled as though capable of transmitting infectious diseases. Universal Precautions should be followed when using this kit. **Not for use by the general public.**
- 7.2 Storage:** Keep away from incompatible materials (Section 10). To maintain efficacy, store according to the package insert instructions.
- 7.3 Specific Use:** *For in vitro diagnostic use only*

### SECTION 8 – Exposure Controls and Personal Protection

#### 8.1 Exposure Limits:

CAS#	Chemical Name	OSHA (PEL)	ACGIH (TLV)	MAK
26628-22-8	Sodium Azide	None	0.29 mg/m <sup>3</sup> (c)	0.2 mg/m <sup>3</sup>

#### 8.2 Occupational Exposure Controls:

##### 8.2.1 Engineering Controls:

No special engineering controls are required when working with this kit. Use with adequate ventilation to ensure exposure levels are maintained below the limits provided above.

##### 8.2.2 Personal Protective Equipment (PPE):

Respiratory Protection:

None needed under normal conditions of use.

Eye Contact:

Safety glasses or face shield are recommended to prevent eye contact.

Hand Contact:

Impervious gloves (nitrile or equivalent) should be worn to prevent hand contact.

Skin Contact:

Lab Coat or similar garment should be worn.

##### 8.2.3 Environmental Controls:

No special environmental controls are required.



## QuickVue® iFOB TEST



### SECTION 9 – Physical and Chemical Properties

Characteristic	FOB Buffer Sodium Azide <0.02%
Boiling Point (°C)	Not Available
Melting Point (°C)	Not available
Specific Gravity	Approximately 1
Vapor Pressure (mm Hg)	Not available
Vapor Density (AIR = 1)	Not available
Evaporation Rate (Ether = 1)	< 1
pH:	Neutral
Solubility in Water:	Soluble
Appearance and Odor:	Clear, Odorless

### SECTION 10 – Stability and Reactivity

Characteristic	FOB Buffer Sodium Azide <0.02%
Stability	Stable
Conditions to Avoid	Incompatible materials
Materials to avoid (Incompatibilities)	Sodium Azide may react with lead and copper plumbing to form highly explosive metal azides. Avoid contact with acid, metals, halogenated solvents, and dimethyl sulfate
Hazardous Decomposition or Byproducts	Nature of decomposition of products non known
Hazardous Polymerization	Will not occur

### SECTION 11 – Toxicological Information

#### 11.1 Toxicity Data for Hazardous Ingredients:

There are currently no toxicity data available for the components of this kit.

#### 11.2 Routes of Exposure:

**Overexposures to components within this kit are not expected.** Common routes of exposure may include ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

#### 11.3 Potential Effects of Acute Overexposure, By Route Of Exposure:

This kit may contain materials of human or animal origin and should be considered as potentially capable of transmitting infectious diseases.

INHALATION: Vapors, mists, sprays, or dusts of this kit can cause irritation to the respiratory tract.

CONTACT WITH SKIN or EYES: Contact can cause eye or skin irritation.

SKIN ABSORPTION: May be harmful if absorbed through skin.

INGESTION: If FOB Buffer is swallowed, irritation of the mouth, throat, and other tissues of the gastro-intestinal system may occur.

INJECTION: Accidental injection of this kit may cause burning, reddening, and swelling in addition to the wound. Symptoms of such exposure can include those described under "Inhalation", "Contact with Skin or Eyes," and "Ingestion".



QuickVue® iFOB TEST



## SECTION 11 – Toxicological Information

### 11.4 Potential Effects of Chronic Exposure:

Long-term skin or eye contact can result in dermatitis or eye irritation. Prolonged or repetitive exposure to Sodium Azide may increase risk of cumulative effects.

### 11.5 Symptoms of Overexposure:

Symptoms of overexposure to Sodium Azide may include: eye, skin, nose, and throat irritation, headache, nausea and vomiting. Symptoms may be delayed for several hours after exposure.

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

### 11.6 Medical Exposure Aggravated by Exposure:

Persons with pre-existing skin disorders; eye problems or impaired respiratory system function can be more susceptible to health effects associated with overexposures to the chemicals within this kit.

### 11.7 Carcinogenicity:

CHEMICAL NAME	ACGIH	IARC	NTP	OSHA
Sodium Azide	No	No	No	No

## SECTION 12 – Ecological Information

### 12.1 Ecotoxicity – Not Available

No adverse effects on the environment are expected from the components of this kit.

### 12.2 Mobility, Persistence and Degradability

Mobility, persistence and degradation data are not available for the components of this kit.

### 12.3 There is limited potential for the components within this kit to accumulate in plant or animal systems.

## SECTION 13 – Disposal Considerations

Dispose of waste materials, unused components and contaminated packaging in compliance with country (i.e., Canada, EU) federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

## SECTION 14 – Transport Information

### 14.1 U.S. Transportation

This substance is considered to be non-hazardous for transport.

### 14.2 Canadian Transportation

The above-listed DOT basic description applies to this product under the regulations of Transport Canada.

### 14.3 International Air Transportation

This substance is considered to be non-hazardous for air transport.



## QuickVue® iFOB TEST



### SECTION 15 – Regulatory Information

#### 15.1 U.S. Federal and State Regulations

Regulatory Reference	FOB Buffer - Sodium Azide <0.02%
40 CFR 355.30/355.40 - SECTION 302	Not applicable
40 CFR 302.4 – SECTION 304	Not applicable
40 CFR 372.65 – SECTION 313	Not applicable

U.S. SARA SECTION 311/312 FOR KIT:

Not applicable

U.S. TSCA INVENTORY STATUS:

Sodium Azide listed on the TSCA Inventory.

OTHER U.S. FEDERAL REGULATIONS:

Not applicable.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No

#### 15.2 Label Information

ANSI 129.1 Not required for component or kit

##### ENVIRONMENTAL HAZARDS:

Do not discharge effluent containing this kit into streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this kit to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

#### 15.3 Canadian Regulations:

##### CANADIAN DSL/NDL INVENTORY STATUS:

Sodium Azide is listed on the DSL Inventory.

##### CANADIAN WHMIS SYMBOLS:

None Required

#### 15.4 HMIS Ratings (See Page 10 for Definition of Ratings):

##### FOB Buffer – Sodium Azide <0.02%

Health	0
Flammability	0
Physical Hazard	0
Protective Equipment	B

**B: Safety Glasses and Gloves**

*Reference Only*

#### 15.5 EU Labeling Classification:

<b>Classification:</b> Non-Hazardous No hazard classification or danger symbol required.	<b>Risk Phrases:</b> N/A <b>Safety Phrases:</b> N/A
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QuickVue® iFOB TEST



## SECTION 16 – Other Information

This MSDS has been prepared in accordance with ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the US OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

The hazard ratings on this MSDS are for appropriately trained workers using the Hazardous Materials Identification System (HMIS®) or a National Fire Protection Association (NFPA) 704 Program. The ratings are estimates and should be treated as such. The hazard rating scales range from (0) minimal hazards to (4) significant hazards or risks (Refer to Definitions of Terms at the end of this MSDS). Chronic (long-term) health effects are indicated in the HMIS by and asterisk (\*). HMIS is a registered trade and service mark of the NPCA. For details on HMIS ratings visit [www.paint.org/hmis](http://www.paint.org/hmis). For details on NFPA 704 visit [www.nfpa.org](http://www.nfpa.org).

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## QuickVue® iFOB TEST



### DEFINITIONS OF TERMS

A large number of abbreviations and acronyms appear on a MSDS. Some of these, which are commonly used, include the following:

**CAS #:** This is the Chemical Abstract Service Number that uniquely identifies each compound.

**ACGIH** - American Conference of Governmental Industrial Hygienists, a professional association that establishes exposure limits.

**TLV** - Threshold Limit Value - an airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers can be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour Time Weighted Average (**TWA**), the 15-minute Short Term Exposure Limit, and the instantaneous Ceiling Level (**C**). Skin absorption effects must also be considered.

**OSHA** - U.S. Occupational Safety and Health Administration

**PEL** - Permissible Exposure Limit - This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (*Federal Register*: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL," is placed next to the PEL that was vacated by Court Order.

**IDLH** - Immediately Dangerous to Life and Health - This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury. **The DFG - MAK** is the Republic of Germany's Maximum Exposure Level, similar to the U.S. PEL. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (**OSHA**). NIOSH issues exposure guidelines called **Recommended Exposure Levels (RELs)**. When no exposure guidelines are established, an entry of **NE** is made for reference. **Protective Equipment** - **A:** Safety Glasses. **B:** Safety glasses and gloves. **C:** Safety glasses, gloves and body protection. **D:** Splash goggles with face shield, gloves and body protection. **E:** Eye protection, gloves and dust mask respiratory protection. **F:** Eye protection, gloves, body protection and dust mask respiratory protection. **G:** Eye protection, gloves and air purifying respiratory protection.

#### HAZARD RATINGS:

**HAZARDOUS MATERIALS IDENTIFICATION SYSTEM:** Health Hazard: **0** (minimal acute or chronic exposure hazard); **1** (slight acute or chronic exposure hazard); **2** (moderate acute or significant chronic exposure hazard); **3** (severe acute exposure hazard; onetime overexposure can cause permanent injury and can be fatal); **4** (extreme acute exposure hazard; single overexposure can be fatal). \* Indicates chronic hazard. Flammability Hazard: **0** (minimal hazard); **1** (materials that require substantial pre-heating before burning); **2** (combustible liquid or solids; liquids with a flash point of 38-93°C [100-200°F]); **3** (Class IB and IC flammable liquids with flash points below 38°C [100°F]); **4** (Class IA flammable liquids with flash points below 23°C [73°F] and boiling points below 38°C [100°F]). Reactivity Hazard: **0** (normally stable); **1** (material that can become unstable at elevated temperatures or which can react slightly with water); **2** (materials that are unstable but do not detonate or which can react violently with water); **3** (materials that can detonate when initiated or which can react explosively with water); **4** (materials that can detonate at normal temperatures or pressures).

**NATIONAL FIRE PROTECTION ASSOCIATION:** Health Hazard: **0** (material that on exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials); **1** (materials that on exposure under fire conditions could cause irritation or minor residual injury); **2** (materials that on intense or continued exposure under fire conditions could cause temporary incapacitation or possible residual injury); **3** (materials that can on short exposure could cause serious temporary or residual injury); **4** (materials that under very short exposure could cause death or major residual injury). Flammability Hazard and Reactivity Hazard: Refer to definitions for "Hazardous Materials Identification System".

**FLAMMABILITY LIMITS IN AIR:** Much of the information related to fire and explosion is derived from the National Fire Protection Association (**NFPA**). Flash Point - Minimum temperature at which a liquid gives off

sufficient vapors to form an ignitable mixture with air. Autoignition Temperature: The minimum temperature required to initiate combustion in air with no other source of ignition. LEL - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. UEL - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

#### TOXICOLOGICAL INFORMATION:

Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: **LD<sub>50</sub>** - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; **LC<sub>50</sub>** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** concentration expressed in parts of material per million parts of air or water; **mg/m<sup>3</sup>** concentration expressed in weight of substance per volume of air; **mg/kg** quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include **TDLo**, the lowest dose to cause a symptom and **TCLo** the lowest concentration to cause a symptom; **TDo**, **LDLo**, **LDo**, **TC**, **TCo**, **LCLo**, and **LCo**, the lowest dose (or concentration) to cause lethal or toxic effects. **BEI** - Biological Exposure Indices, represent the levels of determinants that are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV. Ecological Information: **EC** is the effect concentration in water.

Data from several sources are used to evaluate the cancer-causing potential of the material. The sources and ratings are: **IARC** - the International Agency for Research on Cancer; 1 = Carcinogenic to humans, 2A, 2B = Probably carcinogenic to humans, 3 = Unclassifiable as to carcinogenicity in humans, and 4 = Probably not carcinogenic to humans. **NTP** - the National Toxicology Program; K = Known to be a human carcinogen, and R = Reasonably anticipated to be a human carcinogen. **RTECS** - the Registry of Toxic Effects of Chemical Substances. **OSHA** - Occupational Safety and Health Administration and **CAL/OSHA** - California's subunit of the Occupational Safety and Health Administration; Ca = Carcinogen defined with no further categorization. **ACGIH** - American Conference of Governmental Industrial Hygienists; A1 = Confirmed human carcinogen, A2 = Suspected human carcinogen, A3 = Confirmed animal carcinogen with unknown relevance to humans, A4 = Not classifiable as a human carcinogen, and A5 = Not suspected as a human carcinogen. **NIOSH** - U.S. National Institute for Occupational Safety and Health; Ca = Potential occupational carcinogen, with no further categorization. **EPA** - U.S. Environmental Protection Agency; A = Human carcinogen, B = Probable human carcinogen, C = Possible human carcinogen, D = Not classifiable as to human carcinogenicity, E = Evidence of Non-carcinogenicity for humans, K = Known human carcinogen, L = Likely to produce cancer in humans, CBD = Cannot be determined, NL = Not likely to be carcinogenic in humans, and I = Data are inadequate for an assessment of human carcinogenic potential.

#### REGULATORY INFORMATION:

This section explains the impact of various laws and regulations on the material. **EPA** is the U.S. Environmental Protection Agency. **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **DOT** and **TC** are the U.S. Department of Transportation and the Transport Canada, respectively.

**Superfund Amendments and Reauthorization Act (SARA)**; the Canadian Domestic/Non-Domestic Substances List (**DSL/NDL**); the U.S. Toxic Substance Control Act (**TSCA**); Marine Pollutant status according to the **DOT**; the Comprehensive Environmental Response, Compensation, and Liability Act (**CERCLA or Superfund**); and various state regulations. This section also includes information on the precautionary warnings that appear on a material's industrial package label.





# SAFETY DATA SHEET

## 1. Identification

**Product identifier** ROTARIX LYOPHILIZED VACCINE

**Other means of identification**

**Synonyms**

HUMAN ROTAVIRUS (HRV) VACCINE \* LIVE ATTENUATED HUMAN ROTAVIRUS (HRV) 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. Medicinal Product

**Recommended restrictions**

No other uses are advised.

**Manufacturer/Importer/Supplier/Distributor information**

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

CHEMTREC EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES:

Customer Number: CCN9484

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	%
SUCROSE	SUGAR CANE SUGAR BEET SUGAR CONFECTIONER'S SUGAR ALPHA-D-GLUCOPYRANOSIDE, BETA-D-FRUCTOFURANOSYL GRANULATED SUGAR SUCRALOX	57-50-1	17.4
HUMAN ROTAVIRUS, LIVE ATTENUATED, RIX4414 STRAIN			Not Applicable
Other components below reportable levels			> 80

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

#### 4. First-aid measures

<b>Inhalation</b>	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.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	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.
<b>Most important symptoms/effects, acute and delayed</b>	None known.
<b>Indication of immediate medical attention and special treatment needed</b>	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.
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	Assume that this product is capable of sustaining combustion.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	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.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

#### 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid prolonged exposure. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	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

Not established

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

Components	Type	Value	Form
SUCROSE (CAS 57-50-1)	PEL	5 mg/m <sup>3</sup>	Respirable fraction.

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

Components	Type	Value	Form
		15 mg/m3	Total dust.

**US. ACGIH Threshold Limit Values**

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

**US. NIOSH: Pocket Guide to Chemical Hazards**

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

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	
<b>Appropriate engineering controls</b>	General ventilation normally adequate.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
<b>Other</b>	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
<b>Respiratory protection</b>	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.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	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**

<b>Physical state</b>	Solid.
<b>Form</b>	Powder.Vial.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.

**Upper/lower flammability or explosive limits**

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

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

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions. DO NOT FREEZE - dispose of properly if frozen.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	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

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	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.
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	None known.

### Information on toxicological effects

<b>Acute toxicity</b>	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.
<b>Serious eye damage/eye irritation</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
<b>Respiratory or skin sensitization</b>	
<b>Respiratory sensitization</b>	No studies have been conducted.
<b>Skin sensitization</b>	None known. This product is not expected to cause skin sensitization.
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>Carcinogenicity</b>	Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.

#### 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.

<b>Reproductive toxicity</b>	Contains no ingredient listed as toxic to reproduction
<b>Specific target organ toxicity - single exposure</b>	Not assigned.
<b>Specific target organ toxicity - repeated exposure</b>	Not assigned.
<b>Aspiration hazard</b>	Not established.
<b>Chronic effects</b>	Prolonged inhalation may be harmful.

**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** Not available.

### Biodegradability

#### Percent degradation (Aerobic biodegradation-inherent)

SUCROSE 69 % BOD5

**Bioaccumulative potential** Not available.

### Partition coefficient n-octanol / water (log Kow)

SUCROSE -3

**Mobility in soil** Not available.

**Mobility in general** Not available.

### Volatility

#### Henry's law

SUCROSE < 0 atm m<sup>3</sup>/mol Estimated

**Other adverse effects** Not available.

## 13. Disposal considerations

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

**Local disposal regulations** Dispose in accordance with all applicable regulations.

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

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.

**Contaminated packaging** 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.

### 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 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**

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.

**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**

<b>Issue date</b>	04-11-2014
<b>Revision date</b>	05-06-2017
<b>Version #</b>	07
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 1 Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	Health: 1 Flammability: 0 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.
<b>Revision information</b>	This document has undergone significant changes and should be reviewed in its entirety.

**McKESSON**

SDS DATE: 11.11.15

**\*\*\* SAFETY DATA SHEET\*\*\*****SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**

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

**MANUFACTURED FOR:** McKesson Medical Surgical, Inc.  
 9954 Mayland Drive  
 Richmond, VA 23233

**INFORMATION LINE:** 1-800-777-4908

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

**PRODUCT DESCRIPTION:** N/A

**SECTION 2: COMPOSITION/INFORMATION OF INGREDIENTS**

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

**SECTION 2 NOTES:** N/A

**SECTION 3: HAZARDS IDENTIFICATION**

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

**POTENTIAL HEALTH EFFECTS**

**EYES:** Irritation to eyes if contact occurs

**SKIN:** Irritation to skin if contact occurs

**INGESTION:** Harmful if swallowed

**INHALATION:** Harmful if inhaled

**ACUTE HEALTH HAZARDS:** N/A

**CHRONIC HEALTH HAZARDS:** N/A

**MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE:** N/A

**CARCINOGENICITY**

**OSHA:** N/A

**ACGIH:** N/A

**NTP:** N/A

**IARC:** N/A

**OTHER:** N/A

**SECTION 3 NOTES:** N/A

**SECTION 4: FIRST-AID MEASURES**

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

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

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

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

# MCKESSON

**SDS DATE:** 11.11.15

**NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:** N/A

**SECTION 4 NOTES:** N/A

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## SECTION 5: FIRE-FIGHTING MEASURES

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**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**

<b>HEALTH:</b> N/A	<b>FLAMMABILITY:</b> N/A	<b>REACTIVITY:</b> N/A
<b>OTHER:</b> N/A		

**HMIS HAZARD CLASSIFICATION**

<b>HEALTH:</b> N/A	<b>FLAMMABILITY:</b> N/A	<b>REACTIVITY:</b> N/A
<b>PROTECTION:</b> N/A		

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

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

**UNUSUAL FIRE AND EXPLOSION HAZARDS:** N/A

**HAZARDOUS DECOMPOSITION PRODUCTS:** N/A

**SECTION 5 NOTES:** Non-flammable liquid.

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## SECTION 6: ACCIDENTAL RELEASE MEASURES

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**ACCIDENTAL RELEASE MEASURES:** N/A

**SECTION 6 NOTES:** N/A

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## SECTION 7: HANDLING AND STORAGE

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**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

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**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

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## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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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 (H<sub>2</sub>O = 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

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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

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**SECTION 11: TOXICOLOGICAL INFORMATION**

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TOXICOLOGICAL INFORMATION: N/A

SECTION 11 NOTES: N/A

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**SECTION 12: ECOLOGICAL INFORMATION**

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ECOLOGICAL INFORMATION: N/A

SECTION 12 NOTES: N/A

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**SECTION 13: DISPOSAL CONSIDERATIONS**

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WASTE DISPOSAL METHOD:

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

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**SECTION 14: TRANSPORT INFORMATION**

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**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

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**SECTION 15: REGULATORY INFORMATION**

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**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

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**SECTION 16: OTHER INFORMATION**

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**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

Issuing Date 20-Jul-2012

Revision Date 12-Feb-2015

Revision Number 2

## 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Identifier**

**Product Name** SODIUM CHLORIDE

**Other means of identification**

**Product Code(s)** BDH9286-12KG : BDH9286-2.5KG : BDH9286-250LB : BDH9286-500G : BDH9286-50KG

**Synonyms** No information available.

**Recommended use of the chemical and restrictions on use**

**Recommended Use** For Laboratory Use Only. Not for Drug, Food, or Household use.

**Uses advised against** Not for Human or Animal Drug Use

**Details of the supplier of the safety data sheet**

**Company Address**

VWR International, LLC  
Radnor Corporate Center  
100 Matsonford Road  
Radnor, PA 19087-8660

**Company Phone Number**

610-386-1700

**E-mail Address**

www.vwr.com

**Emergency Telephone Number**

**Emergency Telephone Number** CHEMTREC 800.424.9300  
CANUTEC 613.996.6666

## 2. HAZARDS IDENTIFICATION

**Classification**

**OSHA Regulatory Status**

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

**Label elements**

**Emergency Overview**

**Appearance** White

**Physical State** Granular Powder

**Odor** No information available

**Hazards not otherwise classified (HNOC)**

Not applicable

**Other Information**

• May be harmful if swallowed

Product Code(s) BDH9286-12KG : BDH9286-2.5KG :  
 BDH9286-250LB : BDH9286-500G :  
 BDH9286-50KG - SODIUM  
 CHLORIDE

Revision Date 12-Feb-2015

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	EC No.	Weight %	Trade Secret
Sodium Chloride	7647-14-5	231-598-3	95-100	Not applicable

### 4. FIRST AID MEASURES

#### First Aid Measures

<b>Eye Contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin Contact</b>	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.
<b>Inhalation</b>	Move to fresh air. If not breathing, give artificial respiration.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Rinse mouth.

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

**Most Important Symptoms/Effects** No information available.

#### 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** No information available.

#### Specific Hazards Arising from the Chemical

No information available.

**Hazardous Combustion Products** Sodium/sodium oxides.

#### Explosion Data

**Sensitivity to Mechanical Impact** None.

**Sensitivity to Static Discharge** None.

#### Protective Equipment and Precautions for Firefighters

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

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal precautions, protective equipment and emergency procedures

**Personal Precautions** Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

#### Environmental Precautions

**Product Code(s)** BDH9286-12KG : BDH9286-2.5KG :  
 BDH9286-250LB : BDH9286-500G :  
 BDH9286-50KG - SODIUM  
 CHLORIDE

**Revision Date** 12-Feb-2015

**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** Sweep up and place in closed containers for disposal.

## 7. HANDLING AND STORAGE

**Precautions for Safe Handling**

**Handling** Avoid contact with skin, eyes and clothing. Remove and wash contaminated clothing before re-use. Do not breathe vapors/dust.

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

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

**Incompatible Products** Strong oxidizing agents.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control parameters**

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

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium Chloride 7647-14-5	-	-	

**Appropriate engineering controls**

**Engineering Measures** Showers  
 Eyewash stations  
 Ventilation systems.

**Individual protection measures, such as personal protective equipment**

**Eye/Face Protection** Safety glasses with side-shields.

**Skin and Body Protection** Wear protective gloves/clothing.

**Respiratory Protection** If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

**Hygiene Measures** Handle in accordance with good industrial hygiene and safety practice.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Information on basic physical and chemical properties**

<b>Physical State</b>	Granular Powder	<b>Odor</b>	No information available
<b>Appearance</b>	White	<b>Odor Threshold</b>	No information available
<b>Color</b>	No information available		

<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks • Method</u></b>
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**Product Code(s)** BDH9286-12KG : BDH9286-2.5KG :  
 BDH9286-250LB : BDH9286-500G :  
 BDH9286-50KG - SODIUM  
 CHLORIDE

**Revision Date** 12-Feb-2015

<b>pH</b>	No information available.
<b>Melting point/freezing point</b>	
<b>Boiling Point/Range</b>	No information available. 2575 °F
<b>Flash Point (High in °C)</b>	No information available.
<b>Evaporation Rate</b>	No information available
<b>Flammability (solid, gas)</b>	No information available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No information available.
<b>Lower flammability limit:</b>	No information available.
<b>Vapor pressure</b>	No information available.
<b>Vapor Density</b>	No information available.
<b>Specific Gravity</b>	2.165
<b>Water Solubility</b>	No information available
<b>Solubility in other solvents</b>	No information available.
<b>Partition coefficient</b>	No information available
<b>Autoignition Temperature</b>	
<b>Decomposition Temperature</b>	No information available
<b>Kinematic viscosity</b>	No information available
<b>Dynamic viscosity</b>	No information available.
<b>Explosive Properties</b>	No information available
<b>Oxidizing Properties</b>	No information available

#### Other Information

<b>Softening Point</b>	No information available.
<b>Molecular Weight</b>	No information available
<b>VOC Content</b>	No information available.
<b>Density</b>	No information available
<b>Bulk Density</b>	No information available

### 10. STABILITY AND REACTIVITY

#### Reactivity

No data available

#### Chemical Stability

Stable under recommended storage conditions.

#### Possibility of Hazardous Reactions

None under normal processing.

#### Conditions to Avoid

Extremes of temperature and direct sunlight.

#### Incompatible Materials

Strong oxidizing agents.

#### Hazardous Decomposition Products

Sodium/ sodium Oxides.

### 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

#### **Product Information**

<b>Inhalation</b>	There is no data available for this product.
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**Product Code(s)**BDH9286-12KG : BDH9286-2.5KG :  
 BDH9286-250LB : BDH9286-500G :  
 BDH9286-50KG - SODIUM  
 CHLORIDE

**Revision Date** 12-Feb-2015

**Eye Contact** There is no data available for this product.

**Skin Contact** There is no data available for this product.

**Ingestion** There is no data available for this product.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium Chloride 7647-14-5	= 3 g/kg ( Rat )	> 10 g/kg ( Rabbit )	> 42 g/m <sup>3</sup> ( Rat ) 1 h

#### Information on toxicological effects

**Symptoms** No information available.

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

**Sensitization** No information available.

**Mutagenic Effects** No information available.

**Carcinogenicity** No information available.

Chemical Name	ACGIH	IARC	NTP	OSHA
Sodium Chloride 7647-14-5	-	-	-	-

**Reproductive Toxicity** No information available.

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Aspiration hazard** No information available.

#### Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document .

## 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

0% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Chemical Name	Toxicity to Algae	Toxicity to Fish	Daphnia Magna (Water Flea)
Sodium Chloride 7647-14-5	-	5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static 7050: 96 h Pimephales promelas mg/L LC50 semi-static 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through	1000: 48 h Daphnia magna mg/L EC50 340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static

#### Persistence and Degradability

No information available.

#### Bioaccumulation/Accumulation

No information available.

Chemical Name	Log Pow
Sodium Chloride 7647-14-5	-

**Other Adverse Effects** No information available

**Product Code(s)**BDH9286-12KG : BDH9286-2.5KG :  
 BDH9286-250LB : BDH9286-500G :  
 BDH9286-50KG - SODIUM  
 CHLORIDE

**Revision Date** 12-Feb-2015

### 13. DISPOSAL CONSIDERATIONS

#### Waste treatment methods

**Waste Disposal Method** Dispose of material in accordance with all federal, state, and local regulations.

**Contaminated Packaging** Do not re-use empty containers.

Chemical Name	RCRA - Halogenated Organic Compounds	RCRA - P Series Wastes	RCRA - F Series Wastes	RCRA - K Series Wastes
Sodium Chloride 7647-14-5	-	-	-	-

Chemical Name	California Hazardous Waste Status
Sodium Chloride 7647-14-5	-

### 14. TRANSPORT INFORMATION

**DOT** Not regulated

**IATA** Not regulated

### 15. REGULATORY INFORMATION

#### International Inventories

<b>TSCA</b>	Complies
<b>DSL/NDSL</b>	Complies
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	Complies
<b>IECSC</b>	Complies
<b>KECL</b>	Complies
<b>PICCS</b>	Complies
<b>AICS</b>	Complies

#### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

#### U.S. Federal Regulations

#### **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.

Component	SARA 313 - Threshold Values %
Sodium Chloride 7647-14-5 ( 95-100 )	-

**Product Code(s)** BDH9286-12KG : BDH9286-2.5KG :  
 BDH9286-250LB : BDH9286-500G :  
 BDH9286-50KG - SODIUM  
 CHLORIDE

**Revision Date** 12-Feb-2015

**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

**Clean Water Act**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium Chloride 7647-14-5	-	-	-	-

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs	RQ
Sodium Chloride 7647-14-5	-	-	-

**U.S. State Regulations**

**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

Chemical Name	California Prop. 65
Sodium Chloride - 7647-14-5	-

**U.S. State Right-to-Know Regulations**

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Sodium Chloride 7647-14-5	-	-	-

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

**Canada**

**WHMIS Hazard Class**

Non-controlled

**16. OTHER INFORMATION**

<b>Issuing Date</b>	20-Jul-2012
<b>Revision Date</b>	12-Feb-2015
<b>Revision Note</b>	No information available

**Product Code(s)**BDH9286-12KG : BDH9286-2.5KG :  
BDH9286-250LB : BDH9286-500G :  
BDH9286-50KG - SODIUM  
CHLORIDE

**Revision Date** 12-Feb-2015

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**Disclaimer**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. VWR International and its Affiliates shall not be held liable for any damage resulting from handling.

**End of Safety Data Sheet**



## SAFETY DATA SHEET



## 1. IDENTIFICATION

**Product Name:** Super Sani-Cloth Germicidal Wipe

(SDS 0020-00)

**Date of Preparation:** October 27, 2015

**Recommended use of the chemical and restrictions on use:**

**Recommended use:** Use as a disinfectant on hard, non-porous surfaces. Read and understand the entire label before using. Use only according to label directions. It is a violation of Federal law to use this product in a manner inconsistent to label directions.

**Restrictions on use:** For Professional and Hospital Use.

**Manufacturer/Supplier:** Nice-Pak/PDI, Inc.  
Two Nice-Pak Park  
Orangeburg, NY 10962-1376

**Phone Number:** 1-845-365-1700

**Emergency Phone Number:** PERS: 1-800-633-8253 (Domestic/Canada)  
1-801-629-0667 (International)

## 2. HAZARD(S) IDENTIFICATION

*This product is a colorless to slightly yellow liquid with a alcohol odor impregnated on a wipe. There is a small amount of liquid on the wipe and very small amount of free liquid in the packages.*

**GHS Classification:**

Physical	Health	Environmental
Flammable Solids Category 1	Eye Irritant Category 2A	Not Classified

**Label Elements:**

Danger!



**Hazard Statements:**

Flammable solid

Causes serious eye irritation.

**Precautionary Statements:**

Keep away from heat, sparks, open flames, and hot surfaces. No smoking.

Wash thoroughly after handling.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical attention.

In case of fire: Use water, water fog, dry chemical or carbon dioxide to extinguish.

Super Sani-Cloth Germicidal Wipe  
10/27/15

**Other Hazards:** None known.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Isopropyl Alcohol	67-63-0	55%
Alkyl (60% C14, 32% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides	68391-01-5	0.25%
Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	85409-23-0/ 68956-79-6	0.25%

### 4. FIRST-AID MEASURES

**Description of First Aid Measures:**

**Eye:** Flush eyes with large quantities of water for several minutes. Remove contact lenses if easy to do so. Continue rinsing. Get medical attention if irritation persists.

**Skin:** No first aid should be required. Wash skin with water. Get medical attention if irritation develops or persists.

**Inhalation:** Not a normal route of exposure. If symptoms develop move victim to fresh air. Get medical attention if symptoms develop.

**Ingestion:** Ingestion is unlikely for solid products. No first aid is required for small amounts transferred from hands to mouth.

**Most Important Symptoms/Effects, Acute and Delayed:** Direct contact may cause eye irritation.

**Indication of Immediate Medical Attention and Special Treatment, If Necessary:** None required under normal conditions of use.

### 5. FIRE-FIGHTING MEASURES

**Suitable (and Unsuitable) Extinguishing Media:** Use water, water fog, dry chemical, or carbon dioxide.

**Specific Hazards Arising From the Chemical:** This product is a flammable solid and will burn under fire conditions. Combustion may produce oxides of carbon, ammonia, and chloride compounds.

**Special Protective Equipment and Precautions for Fire-Fighters:** Wear an approved, positive pressure, self-contained breathing apparatus and full protective clothing. Cool fire exposed containers with water. Contain runoff.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures:** Remove all ignition sources such as open flames, spark producing equipment, pilot lights, etc. Use non-sparking tools and equipment. Avoid contact with eyes and skin. Wear appropriate protective clothing as described in Section 8.

**Environmental Hazards:** Avoid releases to the environment. Report spill as required by local and federal regulations.

**Methods and Materials for Containment and Cleaning Up:** Do not reuse towelette. Pick up wipe and place in an appropriate container for infectious waste disposal. Do not flush in toilet.

## 7. HANDLING AND STORAGE

**Precautions for Safe Handling:** None required for normal use. Avoid contact with eyes and skin. Avoid breathing vapors. Refer product label for additional information on use and handling.

Nonrefillable container. Do not reuse or refill this container. Dispose in accordance with all local, state and federal regulations.

**Conditions for Safe Storage, Including Any Incompatibilities:** Store in a cool, dry location away from incompatible materials. Do not store near heat or open flame. Do not contaminate water, food or feed by storage or disposal. For containers: Protect container from physical damage. When not in use keep center cap of lid closed to prevent moisture loss.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure Guidelines:

Isopropyl Alcohol	200 ppm TWA, 400 ppm STEL ACGIH TLV 400 ppm TWA OSHA PEL
Alkyl (60% C14, 32% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides	None Established
Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	None Established

**Appropriate Engineering Controls:** General ventilation is adequate under normal conditions of use. Refer product label for additional information.

### Individual Protection Measures, Such As Personal Protective Equipment:

**Respiratory Protection:** None required for normal use. In case of insufficient ventilation, wear suitable respiratory equipment. Refer product label for additional information.

**Skin Protection:** Avoid contact with skin.

**Eye Protection:** Avoid contact with eyes.

**Other:** None required under normal conditions of use.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b> Colorless to slightly yellow liquid saturated on a wipe	<b>Flammable limits:</b> LEL: 2.5% (Isopropyl Alcohol) UEL: 12% (Isopropyl Alcohol)
<b>Odor:</b> Alcohol odor	<b>Vapor pressure:</b> Not available
<b>Odor Threshold:</b> Not applicable	<b>Vapor density:</b> Not available
<b>pH:</b> 5.75-8.50 (Saturant)	<b>Relative density:</b> 0.892
<b>Melting point/freezing point:</b> -87.9°C (-126.22°F)	<b>Solubility(ies):</b> Soluble in water (Saturant)

Super Sani-Cloth Germicidal Wipe  
10/27/15

(Isopropyl Alcohol)	
<b>Boiling point/range:</b> 82.3°C (180.14°F) (Isopropyl Alcohol)	<b>Partition coefficient (n-octanol/water):</b> Not available
<b>Flash point:</b> 23.9°C (75.0°F)	<b>Auto-ignition temperature:</b> Not available
<b>Evaporation rate:</b> Not available	<b>Decomposition temperature:</b> Not available
<b>Flammability (solid, gas):</b> Flammable solid	

## 10. STABILITY AND REACTIVITY

**Reactivity:** Not reactive under normal conditions of use. This product may react in contact with incompatible materials.

**Chemical Stability:** Stable under normal storage and handling conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.

**Conditions To Avoid:** Keep away from heat, sparks, and open flames.

**Incompatible Materials:** Avoid contact with strong oxidizing agents, strong acids, isocyanates, and chlorine. Do not use on natural marble, windows, unpainted wood or brass, clear plastic or colored grout.

**Hazardous Decomposition Products:** Thermal decomposition may produce oxides of carbon, ammonia, and chloride compounds.

## 11. TOXICOLOGICAL INFORMATION

### Potential Health Effects:

**Eye:** This product is expected to cause moderate irritation to eyes based on test data from the OPPTS 870.2400 Acute Eye Irritation Study which resulted in Toxicity Category II.

**Skin:** No adverse effects are expected. This product is non-irritating based on test data from the OPPTS 870.2500 Acute Skin irritation study.

**Inhalation:** Inhalation of high concentrations of vapors may cause upper respiratory tract irritation, headache and dizziness.

**Ingestion:** Ingestion is unlikely for solid products. This product contains only a small amount of liquid. No adverse effects are expected.

**Chronic Effects:** None known.

**Carcinogenicity:** None of the components of this product are listed as a carcinogen or suspected carcinogen by OSHA, IARC, and NTP.

**Reproductive Effects:** Reproductive harm is not expected from this product.

**Mutagenic Effects:** Not expected to cause mutagenic activity.

### Acute Toxicity:

No toxicity data available for the mixture. The following toxicity data is for the individual components:

Isopropyl Alcohol: Oral rat LD50: 4396 mg/kg, Dermal rabbit LD50: 12800 mg/kg, Inhalation rat LC50: 16970 mg/L/4hr

Alkyl (60% C14, 32% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides: Oral rat LD50: 240 mg/kg, Dermal rat LD50: 1420-2000 mg/kg

Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride: Oral rat LD50: 250 mg/kg



**12. ECOLOGICAL INFORMATION**

**Ecotoxicity:** No data available for this mixture. The following data is for the individual components:

Isopropyl Alcohol: 96 hr LC50 Bluegill (*Lepomis macrochirus*): >1400 mg/L, 48 hr EC50 Daphnia: 13299 mg/L, 72 hr IC50 Algae: 1000 mg/L

Alkyl (60% C14, 32% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides and Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride: 96 hr LC50 Fish: 0.86 ppm, 48 hr EC50 Daphnia: 0.0058-0.016 mg/L

This product is classified as very toxic to the aquatic environment. Releases to the environment should be avoided.

**Persistence and Degradability:** No data available

**Bioaccumulative Potential:** No data available

**Mobility in Soil:** No data available

**Other Adverse Effects:** None known.

**13. DISPOSAL CONSIDERATIONS**

**Towelette Disposal:** Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.

**Dispenser or Container Disposal:** Nonrefillable container. Do not reuse or refill this container. Dispose in accordance with all local, state and federal regulations.

Empty containers or liners may retain some product residues. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. This material and its container must be disposed of in a safe manner. Dispose in accordance with all local, state and federal regulations.

**14. TRANSPORT INFORMATION**

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
US DOT	UN3175	Solids containing flammable liquid, n.o.s. (Isopropyl Alcohol)	4.1	II	None
IMDG	UN3175	Solids containing flammable liquid, n.o.s. (Isopropyl Alcohol)	4.1	II	Yes
IATA	UN3175	Solids containing flammable liquid, n.o.s. (Isopropyl Alcohol)	4.1	II	None

**Special precautions:** None known

**15. REGULATORY INFORMATION****Safety, Health, and Environmental Regulations Specific for the Product In Question:**

This chemical is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use.

**FIFRA Labeling:****Keep Out Of Reach of Children****WARNING****PRECAUTIONARY STATEMENTS****Hazards to Humans & Domestic Animals**

Warning: Causes substantial but temporary eye damage. Do not get in eyes or on clothing. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using restroom. Remove and wash contaminated clothing before reuse.

**Physical or chemical hazard:** Combustible. Do not use or store near heat or open flame. Do not use on natural marble, windows, unpainted wood, brass, clear plastic or colored grout.

**CERCLA 103 Reportable Quantity:** This product is not subject to reporting under CERCLA. Some states have more stringent reporting requirements. Report all spills in accordance with local, state, and federal regulations.

**SARA TITLE III:**

**Hazard Category for Section 311/312:** Acute Health, Fire Hazard

**Section 313 Toxic Chemicals:** This product contains the following chemicals subject to SARA Title III Section 313 Reporting requirements: None

**Section 302 Extremely Hazardous Substances (TPQ):** None

**EPA Toxic Substances Control Act (TSCA) Status:** This product is a EPA Registered product #9480-4. However, all of the ingredients of this product are listed on the TSCA inventory.

**STATE REGULATIONS:**

**California Proposition 65:** This product does not contain a substance known in the State of California to cause cancer and/or reproductive harm.

**CANADIAN REGULATIONS**

**Canadian Environmental Protection Act:** All of the components in this product are listed on the Domestic Substances List (DSL).

Super Sani-Cloth Germicidal Wipe  
10/27/15

**16. OTHER INFORMATION****HMIS Ratings:** Health – 2

Flammability – 3

Physical Hazard - 0

**NFPA Ratings:** Health – 2

Flammability – 3

Instability – 0

**SDS Revision History:** Revision 2. Formatting changed as SDS has been completed by a different vendor. Based on further test data, the following changes have been made: Eye hazard category changed to 2A. Eye hazard statement downgraded. Eye irritation terminology downgraded for precautionary statement and first aid. Precautions for safe handling downgraded. Potential health effects to eyes downgraded.

**Date of preparation:** October 27, 2015**Date of last revision:** December 7, 2017



Conforms to HazCom 2012/United States

# SAFETY DATA SHEET

Testosterone Cypionate Injection, USP C-III



## Section 1. Identification

<b>GHS product identifier</b>	: Testosterone Cypionate Injection, USP C-III
<b>Synonyms</b>	: Not available.
<b>Product code</b>	: NDC 0143-9659-01 NDC 0143-9726-01
<b>Chemical family</b>	: Not available.
<b>Product type</b>	: Pharmaceutical
<b>Container information</b>	: 1 mL vial, 10 mL vial
<b>Identified uses</b>	: Hormone.
<b>Supplier's details</b>	: West-Ward Pharmaceuticals 401 Industrial Way Eatontown NJ 07724 Phone (732 542 1191) Fax (732 720 6220)
<b>Emergency telephone number (with hours of operation)</b>	: CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887 24/7

## Section 2. Hazards identification

<b>OSHA/HCS status</b>	: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
<b>Classification of the substance or mixture</b>	: CARCINOGENICITY - Category 1B TOXIC TO REPRODUCTION (Fertility) - Category 2 TOXIC TO REPRODUCTION (Unborn child) - Category 2 AQUATIC HAZARD (LONG-TERM) - Category 3

### GHS label elements

Hazard pictograms

:



Signal word

: Danger

Hazard statements

: H350 - May cause cancer.  
H361 - Suspected of damaging fertility or the unborn child.  
H412 - Harmful to aquatic life with long lasting effects.

### Precautionary statements

Prevention

: P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P280 - Wear protective gloves. Wear eye or face protection. Wear protective clothing.  
P273 - Avoid release to the environment.

Response

: P308 + P313 - IF exposed or concerned: Get medical attention.

Storage

: P405 - Store locked up.



KMK Regulatory Services

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www.kmkregservices.com www.askdrluc.com www.ghssmart.com



## Section 2. Hazards identification

- Disposal** : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Hazards not otherwise classified** : None known.
- Hazards not otherwise classified (HNOC)** : None known.

## Section 3. Composition/information on ingredients

- Substance/mixture** : Mixture
- Other means of identification** : Not available.

### CAS number/other identifiers

- CAS number** : Not applicable.

Ingredient name	%	CAS number
Testosterone Cypionate	10 - 30	58-20-8
Benzyl benzoate	10 - 30	120-51-4
Cottonseed oil	30 - 60	8001-29-4
Benzyl Alcohol	0.1 - 1	100-51-6

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

## Section 4. First aid measures

### Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Flush contaminated skin with plenty of water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

### Most important symptoms/effects, acute and delayed



## Section 4. First aid measures

### Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

### Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Adverse symptoms may include the following:  
     reduced fetal weight  
     increase in fetal deaths  
     skeletal malformations
- Skin contact** : Adverse symptoms may include the following:  
     reduced fetal weight  
     increase in fetal deaths  
     skeletal malformations
- Ingestion** : Adverse symptoms may include the following:  
     reduced fetal weight  
     increase in fetal deaths  
     skeletal malformations

### Indication of immediate medical attention and special treatment needed, if necessary

**Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

**Specific treatments** : No specific treatment.

**Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

## Section 5. Fire-fighting measures

### Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

**Specific hazards arising from the chemical** : This material is harmful to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

**Hazardous thermal decomposition products** : Decomposition products may include the following materials:  
     carbon dioxide  
     carbon monoxide

**Special protective actions for fire-fighters** : No special measures are required.

**Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

### Methods and materials for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

## Section 7. Handling and storage

### Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. Avoid release to the environment. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.



## Section 8. Exposure controls/personal protection

### Control parameters

#### Occupational exposure limits

None.

#### **Appropriate engineering controls**

: If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

#### **Environmental exposure controls**

: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

### Individual protection measures

**Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

#### **Eye/face protection**

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

### Skin protection

#### **Hand protection**

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

#### **Body protection**

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

#### **Other skin protection**

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

#### **Respiratory protection**

: Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

## Section 9. Physical and chemical properties

### Appearance

#### **Physical state**

: Liquid.

#### **Color**

: Clear to Yellow.

#### **Odor**

: Not available.

#### **Odor threshold**

: Not available.

#### **pH**

: Not available.

#### **Melting point**

: Not available.

#### **Boiling point**

: Not available.

#### **Flash point**

: Not available.

## Section 9. Physical and chemical properties

<b>Evaporation rate</b>	: Not available.
<b>Flammability (solid, gas)</b>	: Not available.
<b>Lower and upper explosive (flammable) limits</b>	: Not available.
<b>Vapor pressure</b>	: Not available.
<b>Vapor density</b>	: Not available.
<b>Relative density</b>	: Not available.
<b>Solubility in water</b>	: Not available.
<b>Partition coefficient: n-octanol/water</b>	: Not available.
<b>Auto-ignition temperature</b>	: Not available.
<b>Decomposition temperature</b>	: Not available.
<b>Viscosity</b>	: Not available.

## Section 10. Stability and reactivity

<b>Reactivity</b>	: No specific test data related to reactivity available for this product or its ingredients.
<b>Chemical stability</b>	: The product is stable.
<b>Possibility of hazardous reactions</b>	: Under normal conditions of storage and use, hazardous reactions will not occur.
<b>Conditions to avoid</b>	: No specific data.
<b>Incompatible materials</b>	: Reactive or incompatible with the following materials: oxidizing materials, reducing materials, acids and alkalis.
<b>Hazardous decomposition products</b>	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Benzyl benzoate	LD50 Dermal LD50 Oral	Rabbit Rat	4 g/kg 2800 mg/kg	- -

#### Irritation/Corrosion

There is no data available.

#### Sensitization

There is no data available.

#### Mutagenicity

There is no data available.

#### Carcinogenicity

There is no data available.

#### Reproductive toxicity

There is no data available.

## Section 11. Toxicological information

### Teratogenicity

There is no data available.

### Specific target organ toxicity (single exposure)

There is no data available.

### Specific target organ toxicity (repeated exposure)

There is no data available.

### Aspiration hazard

There is no data available.

**Information on the likely routes of exposure** : Dermal contact. Eye contact. Inhalation. Ingestion.

### Potential acute health effects

**Eye contact** : No known significant effects or critical hazards.  
**Inhalation** : No known significant effects or critical hazards.  
**Skin contact** : No known significant effects or critical hazards.  
**Ingestion** : No known significant effects or critical hazards.

### Symptoms related to the physical, chemical and toxicological characteristics

**Eye contact** : No known significant effects or critical hazards.  
**Inhalation** : Adverse symptoms may include the following:  
     reduced fetal weight  
     increase in fetal deaths  
     skeletal malformations  
**Skin contact** : Adverse symptoms may include the following:  
     reduced fetal weight  
     increase in fetal deaths  
     skeletal malformations  
**Ingestion** : Adverse symptoms may include the following:  
     reduced fetal weight  
     increase in fetal deaths  
     skeletal malformations

### Delayed and immediate effects and also chronic effects from short and long term exposure

#### Short term exposure

**Potential immediate effects** : No known significant effects or critical hazards.  
**Potential delayed effects** : No known significant effects or critical hazards.

#### Long term exposure

**Potential immediate effects** : No known significant effects or critical hazards.  
**Potential delayed effects** : No known significant effects or critical hazards.

### Potential chronic health effects

**General** : No known significant effects or critical hazards.  
**Carcinogenicity** : May cause cancer. Risk of cancer depends on duration and level of exposure.  
**Mutagenicity** : No known significant effects or critical hazards.  
**Teratogenicity** : Suspected of damaging the unborn child.  
**Developmental effects** : No known significant effects or critical hazards.



Testosterone Cypionate Injection, USP C-III

## Section 11. Toxicological information

**Fertility effects** : Suspected of damaging fertility.

### Numerical measures of toxicity

#### Acute toxicity estimates

Route	ATE value
Oral	2500 mg/kg
Dermal	20000 mg/kg

## Section 12. Ecological information

### Toxicity

There is no data available.

### Persistence and degradability

There is no data available.

### Bioaccumulative potential

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
Benzyl benzoate	3.97	-	low

### Mobility in soil


**Soil/water partition coefficient (K<sub>oc</sub>)** : 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.





WEST-WARD

PHARMACEUTICALS

Testosterone Cypionate Injection, USP C-III

Section 14. Transport information

	DOT	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

**AERG** : Not applicable.

**Special precautions for user** : **Transport within user's premises**: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** : Not available.

## Section 15. Regulatory information

**U.S. Federal regulations** : **TSCA 8(a) CDR Exempt/Partial exemption**: Not determined  
**United States inventory (TSCA 8b)**: Not determined.

**Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)** : Not listed

**Clean Air Act Section 602 Class I Substances** : Not listed

**Clean Air Act Section 602 Class II Substances** : Not listed

**DEA List I Chemicals (Precursor Chemicals)** : Not listed

**DEA List II Chemicals (Essential Chemicals)** : Not listed

### SARA 302/304

#### Composition/information on ingredients

No products were found.

**SARA 304 RQ** : Not applicable.

### SARA 311/312

**Classification** : Delayed (chronic) health hazard





Testosterone Cypionate Injection, USP C-III

## Section 15. Regulatory information

### Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Benzyl benzoate	≥10 - <25	No.	No.	No.	Yes.	No.
Testosterone Cypionate	≥10 - <25	No.	No.	No.	No.	Yes.

### SARA 313

No products were found.

### State regulations

- Massachusetts** : None of the components are listed.  
**New York** : None of the components are listed.  
**New Jersey** : None of the components are listed.  
**Pennsylvania** : The following components are listed: Cottonseed Oil; Testosterone esters

### California Prop. 65

**WARNING:** This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Ingredient name	Cancer	Reproductive	No significant risk level	Maximum acceptable dosage level
Testosterone Cypionate	No.	Yes.	No.	No.

## Section 16. Other information

### History

- Date of issue mm/dd/yyyy** : 09/16/16  
**Version** : 2  
**Prepared by** : KMK Regulatory Services Inc.  
**Key to abbreviations** : ATE = Acute Toxicity Estimate  
 BCF = Bioconcentration Factor  
 GHS = Globally Harmonized System of Classification and Labelling of Chemicals  
 IATA = International Air Transport Association  
 IBC = Intermediate Bulk Container  
 IMDG = International Maritime Dangerous Goods  
 LogPow = logarithm of the octanol/water partition coefficient  
 MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)  
 UN = United Nations

### 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.



## 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<sup>®</sup>, Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)

ADACEL<sup>®</sup>, Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed

DAPTACEL<sup>®</sup>, Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

DECAVAC<sup>®</sup>, 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<sup>®</sup>, Influenza Virus Vaccine (All presentations)

Imogam<sup>®</sup> Rabies-HT, Rabies Immune Globulin (Human) USP Heat Treated

IMOVAX<sup>®</sup> RABIES, Rabies Vaccine

IPOL<sup>®</sup>, Poliovirus Vaccine Inactivated

Menactra<sup>®</sup>, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine

Menomune<sup>®</sup> -A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined

Pentacel<sup>®</sup>, Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine

Tetanus Toxoid Adsorbed

TheraCys<sup>®</sup>, BCG Live (Intravesical)

Tripedia<sup>®</sup>, Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

**Tubersol<sup>®</sup>, Tuberculin Purified Protein Derivative (Mantoux)**

**Typhim Vi<sup>®</sup>, Typhoid Vi Polysaccharide Vaccine**

**YF-VAX<sup>®</sup>, 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.**

Sanofi Pasteur Inc. provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. Individuals receiving this information must exercise their independent judgment in determining its appropriateness for a particular purpose. Sanofi Pasteur Inc. makes no representations, or warranties, either express or implied, of merchantability, fitness for a particular purpose with respect to the information set forth herein or to the product to which the information refers. Accordingly, Sanofi Pasteur Inc. will not be responsible for damages resulting from use of or reliance upon this information.



## SAFETY DATA SHEET



## Virex TB Ready-To-Use Disinfectant Cleaner

Version Number: 1

Preparation date: 2014-10-09

## 1. IDENTIFICATION

**Product name:** Virex TB Ready-To-Use Disinfectant Cleaner  
**Product Code:** 04743  
**SDS #:** MS0800547  
**Recommended use:**

- Industrial/Institutional
- Disinfectant
- This product is intended to be used neat.

**Uses advised against:** Uses other than those identified are not recommended

**Manufacturer, importer, supplier:**

US Headquarters Diversey, Inc. 8310 16th St. Sturtevant, Wisconsin 53177-1964 Phone: 1-888-352-2249 MSDS Internet Address: www.diversey.com	Canadian Headquarters Diversey, Inc. - Canada 3755 Laird Road Mississauga, Ontario L5L 0B3 Phone: 1-800-668-3131
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**Emergency telephone number:** 1-800-851-7145 (U.S.); 1-651-917-6133 (Int'l)

## 2. HAZARDS IDENTIFICATION

**Classification for the undiluted product**

Serious eye damage/eye irritation	Category 2A
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**Signal Word:****Warning****Precautionary Statements****CAUSES SERIOUS EYE IRRITATION.**

Avoid contact with eyes, skin and clothing. Wash affected areas thoroughly after handling. May cause irritation to mouth, throat and stomach. Wear chemical-splash goggles and chemical-resistant gloves. IF SWALLOWED: Rinse mouth. Drink a cupful of milk or water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. If eye irritation persists: Get medical advice or attention. Dispose of in accordance with all federal, state and local applicable regulations. SUPPLEMENTAL INFORMATION. May be mildly irritating to skin. In case of contact, immediately flush with plenty of water. If irritation occurs and persists, get medical attention.

**Health hazards not otherwise classified (HHNOC)** - Not applicable**Physical hazards not otherwise classified (PHNOC)** - Not applicable

**Classification for the diluted product @ RTU**

This product is intended to be used neat.

**Precautionary Statements**

See undiluted product information above.

**3. COMPOSITION/INFORMATION ON INGREDIENTS****Classified Ingredients**

Ingredient(s)	CAS #	Weight %
Diethylene glycol butyl ether	112-34-5	5 - 10%
Tetrasodium salt of EDTA	64-02-8	1% - < 3%
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	68391-01-5	> 0.1% - < 1%
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	68956-79-6	> 0.1% - < 1%

\*Exact percentages are being withheld as trade secret information

**4. FIRST AID MEASURES****Undiluted Product:**

**Eyes:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

**Skin:** In case of contact, immediately flush with plenty of water. If irritation occurs and persists, get medical attention.

**Inhalation:** No specific first aid measures are required.

**Ingestion:** IF SWALLOWED: Rinse mouth. Drink a cupful of milk or water.

**Most Important Symptoms/Effects:** No information available.

**Immediate medical attention and special treatment needed:** Not applicable.

**Aggravated Medical Conditions:** Persons with pre-existing skin disorders may be more susceptible to irritating effects.

**Diluted Product:**

This product is intended to be used neat.

**Eyes:** See undiluted product information above.

**Skin:** See undiluted product information above.

**Inhalation:** See undiluted product information above.

**Ingestion:** See undiluted product information above.

**5. FIRE-FIGHTING MEASURES**

**Specific methods:**

No special methods required

**Suitable extinguishing media:**

The product is not flammable. Extinguish fire using agent suitable for surrounding fire.

**Specific hazards:**

Not applicable.

**Special protective equipment for firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

**Extinguishing media which must not be used for safety reasons:** No information available.

**6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions:**

Put on appropriate personal protective equipment (see Section 8.).

**Environmental precautions**

Clean-up methods - large spillage. Soak up with inert absorbent material. Sweep up and shovel into

**and clean-up methods:**

suitable containers for disposal. Use a water rinse for final clean-up.

**7. HANDLING AND STORAGE**

**Handling:** Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Do not taste or swallow. FOR COMMERCIAL AND INDUSTRIAL USE ONLY.

**Storage:**

Protect from freezing. Keep tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

**Aerosol Level (if applicable) :** Not applicable

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure Guidelines:**

Ingredient(s)	CAS #	ACGIH	OSHA
Diethylene glycol butyl ether	112-34-5	10 ppm (TWA)	-
Tetrasodium salt of EDTA	64-02-8	-	-
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	68956-79-6	-	-
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	68391-01-5	-	-

**Undiluted Product:****Engineering measures to reduce exposure:**

No special ventilation requirements General room ventilation is adequate

**Personal Protective Equipment**

<b>Eye protection:</b>	Chemical-splash goggles.
<b>Hand protection:</b>	Chemical-resistant gloves.
<b>Skin and body protection:</b>	No special requirements under normal use conditions.
<b>Respiratory protection:</b>	No special requirements under normal use conditions.
<b>Hygiene measures:</b>	Handle in accordance with good industrial hygiene and safety practice.

**Diluted Product:**

This product is intended to be used neat.

**Personal Protective Equipment**

<b>Eye protection:</b>	Chemical-splash goggles.
<b>Hand protection:</b>	Chemical-resistant gloves.
<b>Skin and body protection:</b>	No special requirements under normal use conditions.
<b>Respiratory protection:</b>	No special requirements under normal use conditions.
<b>Hygiene measures:</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. PHYSICAL AND CHEMICAL PROPERTIES:

**Physical State:** Liquid

**Evaporation Rate:** No information available

**Odor threshold:** No information available.

**Melting point/range:** Not determined

**Autoignition temperature:** No information available

**Solubility in other solvents:** No information available

**Density:** 8.44 lbs/gal 1.012 Kg/L

**Bulk density:** No information available

**Flash point:** > 200 °F > 93.3 °C

**Dilution Flash Point:** > 200 °F > 93.3 °C

**Elemental Phosphorus:** 0 % by wt.

**pH:** 12.2

**Dilution pH:** 12.2 @ RTU

**Metal Corrosion:** Not determined

**Explosion limits:** - upper: Not determined - lower: Not determined

**Color:** Clear, Colorless

**Odor:** Lemon Citrus

**Boiling point/range:** Not determined

**Decomposition temperature:** Not determined

**Solubility:** Completely Soluble

**Relative Density (relative to water):** 1.012

**Vapor density:** No information available

**Vapor pressure:** No information available.

**Partition coefficient (n-octanol/water):** No information available

**Viscosity:** No information available

**VOC:** 0.06 % \*

**VOC % by wt. at use dilution** 0.06 % \*

**Flammability (Solid or Gas):** Not applicable

\* - Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Article 2, Consumer Products, Sections 94508

## 10. STABILITY AND REACTIVITY

**Reactivity:**

Not Applicable

**Stability:**

The product is stable

**Hazardous decomposition products:**

Nitrogen oxides (NOx).

**Materials to avoid:**

Acids. Oxidizing agents.

**Conditions to avoid:**

No information available.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure:

Eye contact, Skin contact, Inhalation

### Delayed, immediate, or chronic effects and symptoms from short and long-term exposure

**Skin contact:** May be mildly irritating to skin. Symptoms may include redness and/or transient discomfort.

**Eye contact:** Causes serious eye irritation. Symptoms may include pain, redness, and watering.

**Ingestion:** May be irritating to mouth, throat and stomach. Symptoms may include stomach pain and nausea.

**Inhalation:** May be irritating to nose, throat, and respiratory tract. Symptoms may include coughing and difficulty breathing.

**Sensitization:** No known effects.

### Numerical measures of toxicity

ATE - Oral (mg/kg): >5000

ATE - Inhalatory, mists (mg/l): >20

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity:** No information available.

**Persistence and Degradability:** No information available.

**Bioaccumulation:** No information available.

## 13. DISPOSAL CONSIDERATIONS

**Waste from residues / unused products:** PESTICIDAL WASTE - Observe all applicable Federal/Provincial/State regulations and Local/Municipal ordinances regarding disposal of pesticide wastes. This product, as sold, if discarded or disposed, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Dispose in compliance with all Federal, state, provincial, and local laws and regulations.

**Contaminated Packaging:** Do not re-use empty containers.

**RCRA Hazard Class (undiluted product):** Not Regulated

## 14. TRANSPORT INFORMATION

**DOT/TDG/IMDG:** Please refer to the Diversey HazMat Library, only available through Internet Explorer, <http://naextranet.diversey.com/dot/>, for up to date shipping information.

**DOT (Ground) Bill of Lading Description:** DISINFECTANTS

**IMDG (Ocean) Bill of Lading Description:** DISINFECTANTS

## 15. REGULATORY INFORMATION

### International Inventories at CAS# Level

All components of this product are listed on the following inventories: U.S.A. (TSCA).

### U.S. Regulations

EPA Reg. No. : 70627-2

This chemical is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use.

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and aquatic invertebrates.

**California Proposition 65:** This product is not subject to the reporting requirements under California's Proposition 65.

**RIGHT TO KNOW (RTK)**

Ingredient(s)	CAS #	MARTK:	NJRTK:	PARTK:	RIRTK:
Water	7732-18-5	-	-	-	-
Diethylene glycol butyl ether	112-34-5	-	X	-	-
Tetrasodium salt of EDTA	64-02-8	-	-	-	-
Alcohol ethoxylates	68131-39-5	-	-	-	-
Sodium metasilicate	6834-92-0	-	-	-	-
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	68391-01-5	-	-	-	-
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	68956-79-6	-	-	-	-

**CERCLA/ SARA**

Ingredient(s)	CAS #	Weight %	CERCLA/SARA RQ (lbs)	Section 302 TPQ (lbs)	Section 313
Diethylene glycol butyl ether	112-34-5	5 - 10%			X

Ingredient(s)	CAA HAP	CAA ODS	CWA Priority Pollutants
Diethylene glycol butyl ether	X		

**SARA 311/312 Hazard Categories**

Immediate:	x
Delayed:	-
Fire:	-
Reactivity:	-
Sudden Release of Pressure:	-

**Canada**

WHMIS hazard class: Not for sale in Canada.

Ingredient(s)	CAS #	NPRI
Diethylene glycol butyl ether	112-34-5	X

**16. OTHER INFORMATION****NFPA (National Fire Protection Association)**

Rating Scale: (Low Hazard) 0 - 4 (Extreme Hazard)

Health 2

Flammability 0

Instability 0

Version Number: 1

Preparation date: 2014-10-09

Reason for revision: Not applicable

Prepared by: NAPRAC

Additional advice: • Contains an added fragrance, see "Odor" heading in section 9 for specific description

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