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

Product Identifier

Material Name: Dobutamine in 5% Dextrose Injection, USP (Hospira Inc.)

Trade Name: Dobutamine in 5% Dextrose Injection, USP

Chemical Family: Not determined

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

Intended Use: Pharmaceutical product used as cardiovascular drug

Details of the Supplier of the Safety Data Sheet

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

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

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

Other Hazards

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

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dobutamine Hydrochloride</td>
<td>49745-95-1</td>
<td>256-464-1</td>
<td>Eye Dam 1 (H318)</td>
<td>&lt;0.4</td>
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<tr>
<td>Sodium Hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr. 1A (H314)</td>
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<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>STOT SE 3 (H335)</td>
<td>**</td>
</tr>
<tr>
<td>Sodium metabisulphite</td>
<td>8681-57-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Disodium EDTA (dihydrate)</td>
<td>6381-92-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<tr>
<td>Dextrose, monohydrate</td>
<td>5996-10-1</td>
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<td>Not Listed</td>
<td>5</td>
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<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
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</table>

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:** Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.
- **Skin Contact:** Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
- **Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- **Inhalation:** Move to fresh air If discomfort occurs, get medical attention.

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

Indication of the Immediate Medical Attention and Special Treatment Needed
- **Notes to Physician:** None

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture
- **Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire. May include oxides of carbon.
Fire / Explosion Hazards: Not applicable

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

6. ACCIDENTAL RELEASE MEASURES

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

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

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

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

7. HANDLING AND STORAGE

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

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Incompatible Materials: None known
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.

Dobutamine Hydrochloride
Pfizer OEL TWA-8 Hr: 300µg/m³, Severe Eye Irritant

SODIUM HYDROXIDE
ACGIH Ceiling Threshold Limit: 2 mg/m³
Australia PEAK 2 mg/m³
Austria OEL - MAKs 2 mg/m³
Bulgaria OEL - TWA 2.0 mg/m³
Czech Republic OEL - TWA 1 mg/m³
Estonia OEL - TWA 1 mg/m³
France OEL - TWA 2 mg/m³
Greece OEL - TWA 2 mg/m³
Hungary OEL - TWA 2 mg/m³
Japan - OELs - Ceilings 2 mg/m³
Latvia OEL - TWA 0.5 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country/Organization</th>
<th>Limit Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA - Final PELs - TWAs</td>
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<td>2 mg/m³</td>
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<tr>
<td>Poland OEL - TWA</td>
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<td>0.5 mg/m³</td>
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<tr>
<td>Slovakia OEL - TWA</td>
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<td>2 mg/m³</td>
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<tr>
<td>Slovenia OEL - TWA</td>
<td></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td></td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

**HYDROCHLORIC ACID**

<table>
<thead>
<tr>
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<th>Limit Type</th>
<th>Value</th>
</tr>
</thead>
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<tr>
<td>ACGIH Ceiling Threshold Limit</td>
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<tr>
<td>Australia PEAK</td>
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<td></td>
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<tr>
<td>Austria OEL - MAKs</td>
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<td></td>
<td></td>
<td>8 mg/m³</td>
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<td>Belgium OEL - TWA</td>
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<td></td>
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<td>8 mg/m³</td>
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<td>Bulgaria OEL - TWA</td>
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<td>Cyprus OEL - TWA</td>
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<td>8 mg/m³</td>
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<tr>
<td>Germany - TRGS 900 - TWAs</td>
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<tr>
<td></td>
<td></td>
<td>3 mg/m³</td>
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<tr>
<td>Germany (DFG) - MAK</td>
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<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.0 mg/m³</td>
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<td>Greece OEL - TWA</td>
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<tr>
<td></td>
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<td>7 mg/m³</td>
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<tr>
<td>Hungary OEL - TWA</td>
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<td></td>
<td></td>
<td>8 mg/m³</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
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<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.0 mg/m³</td>
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<td>Latvia OEL - TWA</td>
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<td></td>
<td></td>
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<tr>
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<td></td>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Luxembourg OEL - TWA</td>
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<td></td>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Malta OEL - TWA</td>
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<td></td>
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<tr>
<td>Netherlands OEL - TWA</td>
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<td>8 mg/m³</td>
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<td>Poland OEL - TWA</td>
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<td>5 mg/m³</td>
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<td>Portugal OEL - TWA</td>
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<td></td>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Romania OEL - TWA</td>
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<tr>
<td></td>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td></td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8.0 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Personal Protective Equipment:

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 goggles if eye contact is possible (face shield recommended if splashing 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. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Odor: No data available.
Molecular Formula: Mixture

Solvent Solubility: No data available
Water Solubility: Soluble
pH: 2.5-5.5
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

Physical and chemical properties of Dobutamine in 5% Dextrose Injection, USP include:

- **Material Name:** Dobutamine in 5% Dextrose Injection, USP (Hospira Inc.)
- **Odor:** No data available
- **Molecular Formula:** Mixture
- **Solvent Solubility:** No data available
- **Water Solubility:** Soluble
- **pH:** 2.5-5.5
- **Melting/Freezing Point (°C):** No data available
- **Boiling Point (°C):** No data available
- **Partition Coefficient:** No data available

Additional remarks:

- **Color:** Colorless
- **Odor Threshold:** No data available
- **Molecular Weight:** Mixture

No data available for:

- **HYDROCHLORIC ACID**
- **SODIUM HYDROXIDE**
- **sodium metabisulphite**
- **Disodium EDTA (dihydrate)**
- **Dextrose, monohydrate**
9. PHYSICAL AND CHEMICAL PROPERTIES

Dobutamine Hydrochloride

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

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

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions
- Oxidizing Properties: None
- Conditions to Avoid: None known
- Incompatible Materials: None known
- Hazardous Decomposition Products: None known

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include headache, nausea, shortness of breath (dyspnea), palpitations, chest pain, increased heart rate (tachycardia), increase in blood pressure (hypertension).

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

HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

Dobutamine Hydrochloride

Rat Oral LD50 2296 mg/kg

Mouse Oral LD50 1324mg/kg

Rat Intravenous LD50 59.6mg/kg

Mouse Intravenous LD50 34.3mg/kg

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

Dobutamine Hydrochloride

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Corrosive

PZ03085
11. TOXICOLOGICAL INFORMATION

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
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<tr>
<td>Dobutamine Hydrochloride</td>
<td>Rat</td>
<td>No route specified</td>
<td>14.4 mg/kg/day</td>
<td>NOAEL</td>
<td>Not teratogenic</td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>No route specified</td>
<td>28.8 mg/kg/day</td>
<td>NOAEL</td>
<td>Not Teratogenic</td>
</tr>
</tbody>
</table>

HYDROCHLORIC ACID

Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vivo Micronucleus *Rat* Negative

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

HYDROCHLORIC ACID

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

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

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

Dobutamine Hydrochloride
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: 256-464-1

Sodium metabisulphite
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

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

Disodium EDTA (dihydrate)
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

Dextrose, monohydrate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

HYDROCHLORIC ACID
- CERCLA/SARA 313 Emission reporting: 1.0 %
- CERCLA/SARA Hazardous Substances: 5000 lb
- and their Reportable Quantities: 2270 kg
- CERCLA/SARA - Section 302 Extremely Hazardous TPQs: 500 lb
- CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
15. REGULATORY INFORMATION

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
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<td>Schedule 5</td>
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<td><strong>Water for Injection</strong></td>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
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</tr>
<tr>
<td>Australia (AICS):</td>
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<tr>
<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
<td>Present</td>
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<tr>
<td>EU EINECS/ELINCS List</td>
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</tr>
</tbody>
</table>

16. OTHER INFORMATION

**Text of CLP/GHS Classification abbreviations mentioned in Section 3**

- Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
- Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage
- Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

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

**Reasons for Revision:** Updated Section 8 - Exposure Controls / Personal Protection.

**Revision date:** 08-Apr-2019

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

Pfizer Inc believes 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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet