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

Product Identifier

Material Name: Precedex (dexmedetomidine hydrochloride) Injection, Solution (Hospira Inc.)
Trade Name: Precedex
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product used as Sedative/analgesic; alpha-2-adrenergic agonist 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
International CHEMTREC (24 hours): +1-703-527-3887
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

Note: No data available

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

<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>PZ02986</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

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>Dexmedetomidine hydrochloride</td>
<td>145108-58-3</td>
<td>Not Listed</td>
<td>Muta.2 (H341)</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.2 (H361d)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT RE2 (H373)</td>
<td></td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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

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

4. FIRST AID MEASURES

Description of First Aid Measures

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

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

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

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

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards: Fine particles (such as 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
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
Restrict access to work area. 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:
Dexmedetomidine reported to produce violent reactions with BrF3, H2SO4, KMnO4

Specific end use(s):
Pharmaceutical product used as Sedative/analgesic; alpha-2-adrenergic agonist agent

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

SODIUM CHLORIDE
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³

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

Dexmedetomidine hydrochloride

Pfizer Occupational Exposure Band (OEB):
OEB 5 (control exposure to <1µg/m³)

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures.
Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: 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.)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Compartment</th>
<th>Protection Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes</td>
<td>Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the</td>
</tr>
<tr>
<td></td>
<td>standards in accordance with EN166, ANSI Z87.1 or international equivalent.)</td>
</tr>
<tr>
<td>Skin</td>
<td>Impervious disposable protective clothing is recommended if skin contact with drug product is</td>
</tr>
<tr>
<td></td>
<td>possible and for bulk processing operations. (Protective clothing must meet the standards in</td>
</tr>
<tr>
<td></td>
<td>accordance with EN13982, ANSI 103 or international equivalent.)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is</td>
</tr>
<tr>
<td>protection</td>
<td>exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures</td>
</tr>
<tr>
<td></td>
<td>to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must</td>
</tr>
<tr>
<td></td>
<td>meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)</td>
</tr>
</tbody>
</table>

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
<td>No data available</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>No data available</td>
</tr>
<tr>
<td>Dexmedetomidine hydrochloride</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition Temperature (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml)</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability</td>
<td></td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (Solids):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>No data available</td>
</tr>
<tr>
<td>Chemical Stability</td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
<td></td>
</tr>
<tr>
<td>Oxidizing Properties</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td></td>
</tr>
<tr>
<td>Incompatible Materials</td>
<td>Dexmedetomidine reported to produce violent reactions with BrF3, H2SO4, KMnO4</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available.</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxico logical properties have not been thoroughly investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.

Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following intravenous exposure to this compound may include: decrease in blood pressure (hypotension), increase in blood pressure (hypertension), nausea, decreased heart rate (bradycardia), fever, vomiting, increased heart rate (tachycardia), and decreased red blood cell count (anemia).

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

SODIUM CHLORIDE
- Rat Subcutaneous (eye) LC50/1hr > 42 g/m³
- Rat Oral LD 50 3g/kg
- Mouse Oral LD 50 4g/kg
- Rabbit Dermal LD 50 > 10g/kg

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

SODIUM CHLORIDE
- Skin Irritation Rabbit Mild
- Eye Irritation Rabbit Mild

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

Dexmedetomidine hydrochloride
- 28 Day(s) Rat Intravenous Eyes, Adrenal gland, Lungs
- 28 Day(s) Rat Intramuscular Adrenal gland, Eyes, Lungs
- 28 Day(s) Dog Intravenous Liver, Central Nervous System
- 28 Day(s) Dog Intramuscular 10 µg/kg/day NOAEL Liver, Central Nervous System

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

Dexmedetomidine hydrochloride
- Embryo / Fetal Development Rat Subcutaneous 20 ug/kg NOAEL Not teratogenic, Fetotoxicity
- Peri-/Postnatal Development Rat Subcutaneous 2 ug/kg/day NOAEL Fetotoxicity, Developmental toxicity
- Embryo / Fetal Development Rabbit Intravenous 96 ug/kg/day NOAEL Not Teratogenic
- Reproductive & Fertility Rat Subcutaneous 54 ug/kg/day NOAEL Fertility

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

Dexmedetomidine hydrochloride
- In Vitro Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
- In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Negative
- In Vitro Chromosome Aberration Human Lymphocytes Positive with activation, Negative without activation
- In Vivo Micronucleus Mouse Positive

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

Environmental Overview: Environmental properties have not been investigated.
Toxicity: No data available
Persistence and Degradability: No data available
Bio-accumulative Potential: No data available
Mobility in Soil: No data available

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

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

SODIUM CHLORIDE
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
15. REGULATORY INFORMATION

| Australia (AICS):         | Present |
| EU EINECS/ELINCS List    | 231-598-3 |

Water for Injection

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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

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

Revision date: 01-Aug-2016

Prepared by: Product Stewardship Hazard Communication

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