



SAFETY DATA SHEET

Revision date: 01-Aug-2016

Version: 1.0

Page 1 of 7

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

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

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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
------------	------------	-----------------------------	--------------------	---

SAFETY DATA SHEET

Material Name: Precedex (dexmedetomidine hydrochloride)
Injection, Solution (Hospira Inc.)
Revision date: 01-Aug-2016

Page 2 of 7

Version: 1.0

3. COMPOSITION / INFORMATION ON INGREDIENTS

Dexmedetomidine hydrochloride	145108-58-3	Not Listed	Muta.2 (H341) Repr.2 (H361d) STOT RE2 (H373)	< 0.1
-------------------------------	-------------	------------	--	-------

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
SODIUM CHLORIDE	7647-14-5	231-598-3	Not Listed	*
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

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.

SAFETY DATA SHEET

Material Name: Precedex (dexmedetomidine hydrochloride)
Injection, Solution (Hospira Inc.)
Revision date: 01-Aug-2016

Page 3 of 7

Version: 1.0

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

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 <1ug/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.)

SAFETY DATA SHEET

Material Name: Precedex (dexmedetomidine hydrochloride)
Injection, Solution (Hospira Inc.)
Revision date: 01-Aug-2016

Page 4 of 7

Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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

SODIUM CHLORIDE

No data available

Water for Injection

No data available

Dexmedetomidine hydrochloride

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: Dexmedetomidine reported to produce violent reactions with BrF3, H2SO4, KMnO4
Hazardous Decomposition Products: No data available

SAFETY DATA SHEET

Material Name: Precedex (dexmedetomidine hydrochloride)
Injection, Solution (Hospira Inc.)
Revision date: 01-Aug-2016

Page 5 of 7

Version: 1.0

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

Toxicological 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 Sub-tenon injection (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 NOEL 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 NOEL Not teratogenic, Fetotoxicity

Peri-/Postnatal Development Rat Subcutaneous 2 ug/kg/day NOEL Fetotoxicity, Developmental toxicity

Embryo / Fetal Development Rabbit Intravenous 96 ug/kg/day NOEL Not Teratogenic

Reproductive & Fertility Rat Subcutaneous 54 ug/kg/day NOEL 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.

SAFETY DATA SHEET

Material Name: Precedex (dexmedetomidine hydrochloride)
Injection, Solution (Hospira Inc.)
Revision date: 01-Aug-2016

Page 6 of 7

Version: 1.0

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

SAFETY DATA SHEET

Material Name: Precedex (dexmedetomidine hydrochloride)
Injection, Solution (Hospira Inc.)
Revision date: 01-Aug-2016

Page 7 of 7

Version: 1.0

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
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