SAFETY DATA SHEET

Product Name: Precedex (dexmedetomidine hydrochloride) Injection, Solution

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-emergency	224 212-2000
Product Name	Precedex (dexmedetomidine hydrochloride) Injection, Solution
Synonyms	(+)-4-(S)-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole monohydrochloride

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Precedex (dexmedetomidine hydrochloride) Injection is a solution containing dexmedetomidine hydrochloride, the dextro-enantiomer of the racemic mixture of medetomidine. Dexmedetomidine is a selective alpha 2-adrenergic receptor agonist used clinically as a pre-operative adjunct of general anesthesia. In the workplace, dexmedetomidine hydrochloride should be considered a potent drug. Evaluation of potential occupational exposures should include consideration of the dermal route. Based on clinical use, possible target organs include the central nervous system and the cardiovascular system.

U.S. OSHA GHS Classification

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

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

Label Element(s)

Pictogram	NA
Signal Word	NA
Hazard Statement(s)	NA

Precautionary Statement(s)

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Dexmedetomidine Hydrochloride
Chemical Formula $C_{13}H_{16}N_2$ •HCl

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Dexmedetomidine Hydrochloride	≤ 0.01	145108-58-3	NI5156750

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride.

4. FIRST AID MEASURES

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

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

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

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

5. FIRE FIGHTING MEASURES

Flammability None anticipated from this aqueous product.

Fire & Explosion Hazard None anticipated from this aqueous product.

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

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

6. ACCIDENTAL RELEASE MEASURES

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

7. HANDLING AND STORAGE

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

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

Special Precautions No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

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

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

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

Skin Protection If skin contact with the product solution is likely, the use of latex or nitrile gloves is recommended.

Eye Protection Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Dexmedetomidine hydrochloride is a white or almost white powder. Precedex Injection is a clear, colorless, isotonic solution.
Odor	NA
Odor Threshold	NA
pH	4.5 to 7.0.
Melting point/Freezing point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	Freely soluble in water
log Partition coefficient: n-octanol/water:	2.89 at pH 7.4
Auto-ignition temperature	NA
Decomposition temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	Not determined. Dexmedetomidine reported to produce violent reactions with BrF_3, H_2SO_4 and $KMnO_4$.
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Not determined for the product formulation or active ingredient dexmedetomidine. By analogy, information for the racemic medetomidine hydrochloride mixture is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
*Medetomidine Hydrochloride	100	LD50	Oral	31	mg/kg	Rat

LD 50: Dosage that produces 50% mortality.
*Pfizer MSDS for Medetomidine Hydrochloride Sterile Injectable Solution

Occupational Exposure Potential	Published reports indicate that dexmedetomidine may be absorbed through intact skin. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. In clinical use, adverse effects have included hypotension, hypertension, nausea, bradycardia, fever, vomiting, hypoxia, tachycardia and anemia.
Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/Corrosion	None anticipated from normal handling of this product. Excessive dermal contact with this product may produce sedation and drowsiness.
Ocular Irritation/ Corrosion	None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation and sedation.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. Dexmedetomidine was negative in the Draize guinea pig sensitization assay at induction and challenge concentrations of 0.0591%.
Reproductive Effects	None anticipated from normal handling of this product. Fertility in male or female rats was not affected after daily subcutaneous injections from 10 weeks prior to mating in males and 3 weeks prior to mating and during mating in females at dosages up to 54 mcg/kg. Teratogenic effects were not observed following administration of dexmedetomidine at subcutaneous dosages up to 200 mcg/kg in rats from day 5 to day 16 of gestation and intravenous dosages up to 96 mcg/kg in rabbits when given from day 6 to day 18 of gestation. However, fetal toxicity, as evidenced by increased post-implantation losses and reduced live pups, was observed in rats at subcutaneous dose of 200 mcg/kg. The no-effect dosage was 20 mcg/kg. In another study, dexmedetomidine, administered subcutaneously to pregnant rats from gestation day 16 through nursing, caused lower pup weights at dosages of 8 and 32 mcg/kg as well as fetal and embryocidal toxicity of second generation offspring at a dosage of 32 mcg/kg. Dexmedetomidine also produced delayed motor development in pups at a dose of 32 mcg/kg. No such effects were observed at a dosage of 2 mcg/kg. Placental transfer of dexmedetomidine was observed when radiolabeled dexmedetomidine was administered subcutaneously to pregnant rats.

11. TOXICOLOGICAL INFORMATION: continued

Mutagenicity	None anticipated from normal handling of this product. Dexmedetomidine was not mutagenic *in vitro*, in either the bacterial reverse mutation assay (E. coli and Salmonella typhimurium) or the mammalian cell forward mutation assay (mouse lymphoma). Dexmedetomidine was clastogenic in the *in vitro* human lymphocyte chromosome aberration test with, but not without, metabolic activation. Dexmedetomidine was also clastogenic in the in vivo mouse micronucleus test.
Carcinogenicity	Animal carcinogenicity studies have not been performed with dexmedetomidine.
Carcinogen Lists	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed
Specific Target Organ Toxicity – Single Exposure	Based on clinical use, possible target organs include the central nervous system and the cardiovascular system.
Specific Target Organ Toxicity – Repeat Exposure	NA

12. ECOLOGICAL INFORMATION

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

Notes:

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORTATION INFORMATION

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

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

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

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

GHS/CLP Classification*

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

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

Prevention

Do not breathe vapor or spray
Wash hands thoroughly after handling

Response

Get medical attention if you feel unwell.

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

EU Classification*

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

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

16. OTHER INFORMATION

Notes:

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

MSDS Coordinator:	Hospira GEHS
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