SAFETY DATA SHEET

Dexmedetomidine Hydrochloride Injection, Solution

1) PRODUCT AND COMPANY IDENTIFICATION

Product name:	Dexmedetomidine hydrochloride Injection, Solution
Synonyms:	(+)-4-(S)-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole monohydrochloride
CAS Number:	145108-58-3
Formula:	$C_{13}H_{16}N_2$ •HCl
Chemical Family:	Injection, Solution
Recommended Use:	Injectionable solution – (Prescription Drug to be Administered by Medical Professionals Only)
Manufacturer:	Piramal Critical Care, Inc 268 Brodhead Road Bethlehem, PA 18017
Supplier:	Piramal Critical Care, Inc. 268 Brodhead Road Bethlehem, PA 18017
24 Hour Emergency Number:	CHEMTREC 1-703-527-3887

2) HAZARDS IDENTIFICATION

GHS Classification:

Physical Hazard:	Not classifiable	
Health Hazard:	Specific target organ toxicity - single exposure (narcotic effects)	Category 3

Label Elements:

Signal Word: Warning

Hazard Statements: H336 May cause drowsiness and dizziness

Precautionary Statements:

P261	Do not breathe mist/vapours/spray.
P271	Use in a well ventilated area.
P304 +	IF INHALED: Remove victim to fresh air and keep at rest in a position P340 comfortable for breathing.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/provincial/federal regulations.

3) COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	Classification	CAS #
Dexmedetomidine Hydrochloride	≤ 0.01	None	145108-58-3

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

Flash Point: Not determined

Specific Methods: No information available

Flammable Limits in air-lower (%): N/A

Flammable Limits in air-upper (%): N/A

Auto ignition: N/A

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.

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

Fire and Explosion Hazard: None anticipated from this aqueous product.

6) ACCIDENTAL RELEASE MEASURES

In Case of Spill or Leak: 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.

8) EXPOSURE CONTROLS/PERSONAL PROTECTION

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

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.

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

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.

OSHA-Time Weighted Average: None
OSHA-Short Term Exposure Limit: None
OSHA-Ceiling Limits: None
ACGIH-Time Weighted Average: None
ACGIH-Short Term Exposure Limit: None
ACGIH-Ceiling Limit Value: None
NIOSH REL: None

9) PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Dexmedetomidine hydrochloride is a white or almost white powder. Injection is a clear, colorless, isotonic solution.
Physical State: Powder
Color: White or almost white
Odor: NA
Odor Threshold: NA
pH: 4.5 to 7.0
Molecular Weight: NA
Boiling Point: NA
Melting/Freezing Point: NA
Vapor Pressure: NA
Vapor Density: NA
Relative Density: NA
Evaporation Rate: NA
Water Solubility: Freely soluble in water
% Volatile by Volume: NA

Specific Gravity: NA
Flash Point: N/A
Explosive Limits: N/A
Ignition Temperature: N/A
Flammability (solid/gas): NA
Partition coefficient: 2.89 at pH 7.4
(n-octanol/water)
Viscosity: NA

10) STABILITY AND REACTIVITY

Stability: Stable under standard use and recommended storage conditions.
Incompatibility: Not determined. Dexmedetomidine reported to produce violent reactions with BrF3, H2SO4 and KMnO4.
Polymerization: Not anticipated to occur with this product.
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.
Conditions to Avoid: N/A
Hazardous Reactions: N/A

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

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%.

Respiratory 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.

Carcinogenic Effects: Animal carcinogenicity studies have not been performed with dexmedetomidine.

Mutagenic Effects: 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.

Carcinogen Lists	IARC: 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

Ecotoxicity Effects:	Not determined for product.
Bioaccumulation:	Not determined for product.
Degradability:	Not determined for product.
Mobility:	Not determined for product.

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) TRANSPORT INFORMATION

DOT:	Not regulated
DOT shipping name:	NA
UN number:	NA
Packing Group:	NA
DOT hazard class:	NA
ICAO/IATA: IATA proper shipping name:	Not regulated
IATA UN number:	NA
IATA primary hazard class:	NA
IATA packing group:	NA
IATA packing instruction:	NA
TDG (Canada):	Not regulated
IMO/IMDG:	Not regulated
ADR/RID:	Not regulated

15) REGULATORY INFORMATION

TSCA Inventory List:	This product is exempt from TSCA.
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

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

Disclaimer:

Piramal provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. PIRAMAL MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, PIRAMAL WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

SDS Updates:
06-11-2020 – New Document
7-15-2021 - Added GHS components to section 2.