SAFETY DATA SHEET

1. Identification

Product Identifier: Dexmedetomidine Hydrochloride Injection

Synonyms: Dexmedetomidine HCl; Dexmedetomidine Hydrochloride; (+)-Medetomidine Hydrochlorine; (S)-Medetomidine Hydrochloride; (+)-4-(S)[1-(2,3-Dimethylphenyl)ethyl}-1H-imidazole monohydrochloride.

National Drug Code (NDC): 11695-6967-1

Recommended Use: Pharmaceutical.

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2. Hazard(s) Identification

Physical Hazards: Not classifiable.

Health Hazards: Specific target organ toxicity – single exposure (narcotic effects) Category 3

Symbol(s):

Signal Word: Warning.

Hazard Statement(s):

H336 May cause drowsiness and dizziness.

Precautionary Statement(s):

P261 Do not breathe mist/vapours/spray.

P271 Use in a well ventilated area.

P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position 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.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: 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, a potential occupational reproductive hazard, and possibly irritating to the eyes. Evaluation of potential occupational exposures should include consideration of the dermal route (published reports have indicated that dexmedetomidine may be absorbed through intact skin). Possible target organs include the central nervous system, the cardiovascular system, and possibly the fetus. See product label and/or product insert for additional information.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
(+)-4-(S)-{1-(2,3-dimethylphenyl)ethyl]-1H-imidazole monohydrochloride	145108-58-3	Dexmedetomidine HCl; Dexmedetomidine Hydrochloride; (+)-Medetomidine Hydrochloride; (S)-Medetomidine Hydrochloride	C13H16N2• HCl	236.7	0.01%

*The formula also contains Sodium Chloride, 0.9%; and Water for Injection.

4. First Aid Measures

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of

	the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Dry mouth; nausea; vomiting; fever; fatigue, pale skin; cold hands and feet; shortness of breath; dizziness; decreased concentration; agitation; hypotension; hypertension; bradycardia, hypoxia, tachycardia and anemia. May cause hypersensitivity.
Medical Conditions Aggravated by Exposure:	Pre-existing hypersensitivity any components of this heart disease; impaired liver function; impaired kidney function; central nervous system disorders; pregnancy.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:	Use extinguishing media for type of surrounding fire.
Unsuitable Extinguishing Media:	Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:	These products include carbon oxides, nitrogen oxides, phosphorous oxides and other hazardous products of combustion.
Other Specific Hazards:	Closed containers may explode from the heat of fire.
Special Protective Equipment/ Precautions for Firefighters:	Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions:	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.
Personal Protective Equipment:	For personal protection see section 8.
Methods for Cleaning Up:	Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store away from oxidizers, acids, and bases.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Dexmedetomidine HCl	OEL*: 0.1 µg/m^3, 8 Hour TWA, Skin OEL*: 1 µg/m^3, STEL, Skin

* Occupational Exposure Levels (OELs) have been established by private industry.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Protective laboratory coat, apron, or disposable garment.

9. Physical and Chemical Properties

Physical State/Color:	Liquid/Clear.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	4.5 – 7.0.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Miscible in water.
Partition Coefficient (n-octanol/water):	2.89 at pH=7.4
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Oxidizers, acids, bases.
Hazardous Decomposition Products:	No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	May be harmful if swallowed.
Skin Contact:	May be harmful if absorbed through the skin. May cause irritation.
Eye Contact:	May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Medetomidine	Rat	Oral	LD_{50}	31 mg/kg

Acute Toxicity – Dermal: No data available.
Acute Toxicity – Inhalation: No data available.
Corrosivity: No data available.
Dermal Irritation: No data available.
Eye Irritation: No data available.

Sensitization: Dexmedetomidine was negative in the Draize guinea pig sensitization assay at induction and challenge concentrations of 0.0591%.

Toxicokinetics/Metabolism: No data available.

Target Organ Effects: Based on clinical use, possible target organs include the central nervous system, the cardiovascular system, and possibly the fetus.

Reproductive Effects: 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, feel 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 dexmedetomdine was administered subcutaneously to pregnant rats.

Carcinogenicity: No data available.

National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
Mutagenicity:	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.
Aspiration Hazard:	No data available.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA): This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

Massachusetts: Not listed.
New Jersey: Dexmedetomidine hydrochloride.
Pennsylvania: Dexmedetomidine hydrochloride.
California Proposition 65: Not listed.

16. Other Information

Not made with natural rubber latex.

NFPA Rating:		**HMIS Classification:**	
Health:	2	Health:	2
Flammability:	0	Flammability:	0
Reactivity:	0	Physical Hazard:	0

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