

Dexmedetomidine Hydrochloride Sterile Injectable Solution

(0.5 mg/mL)

Safety Data Sheet



Date of issue: Aug 21, 2025

Version:.00

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Name: Dexmedetomidine Hydrochloride Sterile Injectable Solution (0.5 mg/mL)

1.2. Intended Use of the Product

Dexmedetomidine Hydrochloride is indicated for use as a sedative and analgesic in dogs and cats to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures. Dexmedetomidine Hydrochloride is also indicated for use as a preanesthetic to general anesthesia in dogs and cats.

1.3. Name, Address of the Responsible Party

Felix Pharmaceuticals Private Limited,
25-28 North Wall Quay Dublin 1, Ireland

1.4. Emergency Telephone Number

Emergency Number: Contact Felix Pharmaceuticals Private Limited at 1-833-571-1525.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

This product is classified as not hazardous in accordance with the Globally Harmonized System of Classification and Labelling (GHS).

2.2. Label Elements

None

2.3. Other Hazards

No additional information available.

2.4. Unknown Acute Toxicity (GHS-US)

No additional information available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Ingredient Name

Dexmedetomidine Hydrochloride

3.2. Chemical Formula:

(+)-4-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole monohydrochloride

3.3. Mixture

Component	Approximate Quantity	CAS number
Dexmedetomidine hydrochloride	0.5 mg/mL	145108-58-3
Non-hazardous Ingredients	q.s	Not Applicable

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

First-aid Measures After Inhalation: Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.

First-aid Measures After Skin Contact: In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.

First-aid Measures After Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention immediately.

First-aid Measures After Ingestion: Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries After Inhalation: No data available.

Symptoms/Injuries After Skin Contact: Exposure may cause temporary irritation, redness, or discomfort. May cause skin irritation.

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Symptoms/Injuries After Eye Contact: Direct contact with eyes may cause temporary irritation.

Symptoms/Injuries After Ingestion: May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Chronic Symptoms: Health injuries are not known or expected under normal use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

Alpha2-adrenoreceptor agonist. Treat symptomatically. Monitor respiratory, cardiac and central nervous system. Individuals with cardiac conditions may be more susceptible to toxicity in cases of overexposure.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable Extinguishing Media: Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special Hazards Arising from the Substance or Mixture

Fire Hazard: No unusual fire hazards noted.

Explosion Hazard: No unusual explosion hazards noted.

Reactivity: The product is stable and non-reactive under normal conditions of use.

Special Fire Fighting Procedure: Use standard firefighting procedures and consider the hazards of other involved materials.

5.3. Advice for Firefighters

Precautionary Measures Fire: Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Firefighting Instructions: Move containers from fire area if you can do so without risk.

Protection During Firefighting: Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Keep unnecessary personnel away. Ensure adequate ventilation. Ventilate the contaminated area. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS. Local authorities should be advised if significant spillages cannot be contained..

6.2. Environmental Precautions

Avoid release to the environment. Prevent entry into waterways, sewer, basements or confined areas.

6.3. Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Never return spills to original containers for re-use.

Additional Consideration for Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Additional Consideration for Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

6.4. Reference to Other Sections

For waste disposal, see section 13 of the SDS, and for personal protection, see section 8 of the SDS.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (between 59° and 86°F) [See USP Controlled Room Temperature]. Protect from freezing. In use shelf life: 90 days at 25°C (77°F). Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

Incompatible Products: Strong oxidizing agents.

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7.3. Specific End Use(s)

No data available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

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

8.2. Exposure Controls

Appropriate Engineering Controls	: Keep air contamination levels below the exposure limits. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.
Personal Protective Equipment	: Wear appropriate chemical resistant gloves, safety glasses with side shields (or goggles) and wear suitable protective clothing.
Hand Protection	: Wear appropriate chemical resistant gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eye Protection	: Wear safety glasses with side shields (or goggles).
Skin and Body Protection	: Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory Protection	: No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Solution
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information: No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity : The product is stable and non-reactive under normal conditions of use, storage and transport.
- 10.2. Chemical Stability : Material is stable under normal conditions.

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- 10.3.** Possibility of Hazardous Reactions : No dangerous reaction known under conditions of normal use.
- 10.4.** Conditions to Avoid : Contact with incompatible materials. Exposure to light. High temperatures. Protect from sunlight. Protect from freezing.
- 10.5.** Incompatible Materials : Strong oxidizing agents. BrF₃, H₂SO₄, KMnO₄.
- 10.6.** Hazardous Decomposition Products : Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

SECTION 11: TOXICOLOGICAL INFORMATION

- 11.1.** Acute Toxicity : **Intravenous** LD₅₀ (Dog): 2 mg/kg
- 11.2.** Local Effects : Not Classified
- 11.3.** Reproductive Effects : Not Classified
- 11.4.** Mutagenicity : Not Classified

SECTION 12: ECOLOGICAL INFORMATION

- 12.1.** Toxicity : The product is not classified as environmentally hazardous.
- 12.2.** Persistence and Degradability : No data is available.
- 12.3.** Bio accumulative Potential : No data is available.
- 12.4.** Mobility in Soil : No data is available.
- 12.5.** Other Adverse Effects : No other adverse environmental effects.

SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1. Waste treatment methods**
- Waste Disposal Recommendations** : Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: TRANSPORT INFORMATION

- 14.1.** Transport according to all local, state and federal regulation.

SECTION 15: REGULATORY INFORMATION

- 15.1.** This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

- 16.1. Previous Version** : **Effective Date**
- Nil : Nil

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product. To the best of Felix's knowledge, the information contained here is accurate. However, neither the above-named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All material may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.