

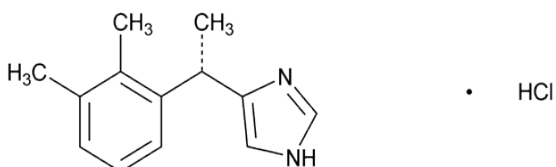
## 1 PRODUCT AND COMPANY INFORMATION

**Distributed By:** WG Critical Care, LLC.  
120 Route 17 North  
Suite 115  
Paramus, NJ 07652 USA

**Product Name:** **DEXMEDETOMIDINE HYDROCHLORIDE INJ**

**Primary Component/ Active Ingredient:** Dexmedetomidine Hydrochloride

**Structure:**



**Chemical Name:** (+)-4-{1-(2,3-dimethylphenyl)ethyl}-1H-imidazole hydrochloride

**Molecular Formula:** C<sub>13</sub>H<sub>17</sub>ClN<sub>2</sub> · HCl

**UNII Code:** 1018WH7F91

**CAS Number:** 145108-58-3

**Chemical Family:** Sedative

**Product Use:** Pharmaceutical

**Product Type:** Prescription Drug

**Container Information:** Plastic bags

**Customer Service Phone Number:** +1-888-493-0861

**Emergency Phone Number:** +1-866-562-4708 (ProPharma)

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## 2 HAZARDS IDENTIFICATION

**Classification of Substance or Mixture:** While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

**Classification of the substance or mixture:** Not classified

**Label Elements:** Signal Word: None  
Hazard Statements: No known significant effects or critical hazards.

**Other Hazards:** None known.

## 3 COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>Weight %</u>	<u>CAS No.</u>
Dexmedetomidine Hydrochloride	0.00040	145108-58-3
Dextrose Monohydrate	**	14431-43-7
Water for Injection	**	7732-18-5

\*\*Additional Information: Ingredients 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.

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## 4 FIRST AID MEASURES

<b>EYE EXPOSURE:</b>	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
<b>SKIN EXPOSURE:</b>	Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.
<b>INGESTION:</b>	Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
<b>INHALATION:</b>	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
<b>NOTE TO PHYSICIAN:</b>	See product package insert. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled

## 5 FIRE FIGHTING MEASURES

<b>EXTINGUISHING MEDIA:</b>	Water mist, extinguishing powder, carbon dioxide. Foam None known.
<b>UNSUITABLE EXTINGUISHING MEDIA:</b>	
<b>SPECIFIC HAZARDS ARISING FROM THE CHEMICAL:</b>	In a fire or if heated, a pressure increase will occur and the container may burst. Fine particles (such as mists) may fuel fires/explosions.
<b>HAZARDOUS DECOMPOSITION PRODUCTS:</b>	Emits toxic fumes when heated.
<b>SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS:</b>	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.  Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.
<b>UNUSUAL FIRE / EXPLOSION HAZARDS:</b>	None known.

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## 6 ACCIDENTAL RELEASE MEASURE

<b>SPILL:</b>	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor.
<b>Personal Precautions, Protective Equipment and Emergency Procedures:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>ENVIRONMENTAL PRECAUTIONS:</b>	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
<b>METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP:</b>	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.
<b>MEASURES FOR CLEANING / COLLECTING:</b>	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.  If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials.
<b>ADDITIONAL CONSIDERATION FOR LARGE SPILLS</b>	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

**GENERAL HANDLING:** Put on appropriate personal protective equipment (see Section 8). Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

**STORAGE CONDITIONS:** Store as directed by product packaging.

## 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

**RESPIRATORY PROTECTION:** Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

**EYE PROTECTION:** Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with sideshields.

**VENTILATION:** Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

**SKIN PROTECTION:** Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

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**ADDITIONAL EXPOSURE PRECAUTIONS:**

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location

## 9 PHYSICAL AND CHEMICAL PROPERTIES

<b>PHYSICAL STATE:</b>	Clear Liquid	<b>SPECIFIC GRAVITY:</b>	Not Available
<b>APPEARANCE AND ODOR:</b>	Not Available	<b>EVAPORATION RATE:</b>	Not Available
<b>BOILING POINT:</b>	Not Available	<b>MELTING POINT:</b>	Not Available
<b>VAPOR PRESSURE:</b>	Not Available	<b>SOLUBILITY IN WATER:</b>	Yes
<b>VAPOR DENSITY:</b>	Not Available	<b>pH:</b>	4.5-7.0

## 10 STABILITY AND REACTIVITY

<b>STABILITY:</b>	This product is stable.
<b>INCOMPATIBILITY : (MATERIALS TO AVOID)</b>	Dexmedetomidine reported to produce violent reactions with BrF <sub>3</sub> , H <sub>2</sub> SO <sub>4</sub> , KMnO <sub>4</sub>
<b>POSSIBILITY OF HAZARDOUS REACTIONS:</b>	Under normal conditions of storage and use, hazardous reactions will not occur.
<b>HAZARDOUS DECOMPOSITION:</b>	Under normal conditions of storage and use, hazardous decomposition products should not be produced
<b>CONDITIONS TO AVOID:</b>	Fine particles (such as mists) may fuel fires/explosions

## 11 TOXICOLOGICAL INFORMATION

### ACUTE TOXICITY

COMPONENT	TYPE	ROUTE	SPECIES	DOSAGE
Medetomidine	LD <sub>50</sub>	Oral	Rat	31 mg/kg

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## 12 ECOLOGICAL INFORMATION

Not available.

## 13 DISPOSAL CONSIDERATIONS

**WASTE DISPOSAL:** The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty Containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

## 14 TRANSPORT INFORMATION

### REGULATORY ORGANIZATIONS:

**DOT:** Not Regulated

**ICAO / IATA:** Not Regulated

**IMO:** Not Regulated

## 15 REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

### US Regulations

TSCA – No

CERCLA-No

SARA 302 – No

SARA 313 – No

OSHA Substance Specific – No

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California Prop 65 – Not Listed

## 16 OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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