



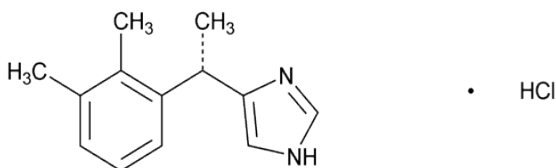
1. PRODUCT AND COMPANY INFORMATION

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: $C_{13}H_{17}ClN_2 \cdot HCl$

UNII Code: UNII-1018WH7F91

CAS Number: 145108-58-3

Chemical Family: Sedative

Product Use: Pharmaceutical
Product Type: Prescription Drug

Container Information: Plastic bags and vials

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

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

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2. HAZARDS IDENTIFICATION

PRIMARY PHYSICAL AND HEALTH HAZARDS: Target organ toxicity-single exposure, toxic if swallowed, inhaled, or skin contact.

ROUTES OF ENTRY: Eye contact; Skin contact; Inhalation; Ingestion; Injection.

SIGNS & SYMPTOMS OF EXPOSURE: 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.

CHEMICAL LISTED AS CARCINOGEN

NTP: NO

IARC: NO

OSHA: NO

3. COMPOSITION / INFORMATION ON INGREDIENTS

| <u>Ingredient</u> | <u>Weight %</u> | <u>CAS No.</u> |
|-------------------------------|-----------------|----------------|
| Dexmedetomidine Hydrochloride | 0.01% | 145108-58-3 |

4. FIRST AID MEASURES

EYE EXPOSURE: Remove from source of exposure. Flush with water for at least 15 minutes. If irritation persists or, seek medical attention. Provide symptomatic/supportive care as necessary.

SKIN EXPOSURE: 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.

INGESTION: Rinse, if swallowed, seek immediate medical attention.

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.

NOTE TO PHYSICIAN: See product package insert.

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5. FIRE FIGHTING MEASURES

| | |
|--|--|
| FLASH POINT: | Not available. |
| AUTO-IGNITION TEMPERATURE: | Not available. |
| FLAMMABLE LIMITS IN AIR: | Not available. |
| FLAMMABLE LIMITS: | Not available. |
| EXTINGUISHING MEDIA: | Suitable: Use extinguishing media for type of surrounding fire. Unsuitable: Not Determined. |
| UNUSUAL FIRE / EXPLOSION HAZARDS: | Toxic and highly corrosive fumes of nitrogen oxides and hydrogen chloride. |
| NOTE TO PHYSICIAN: | Treat supportively and symptomatically. |

6. ACCIDENTAL RELEASE MEASURE

| | |
|--------------------------|---|
| SPILL: | Collect the material, ventilate and wash the area |
| RELEASE TO AIR: | Not available. |
| RELEASE TO WATER: | Not available. |

7. HANDLING AND STORAGE

| | |
|----------------------------|--|
| GENERAL HANDLING: | Avoid contact with eyes and skin. Do not breathe dust. |
| STORAGE CONDITIONS: | Store in airtight containers at room temperature. |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATORY PROTECTION: Particle filtering device (P#) or compressed air line breathing apparatus.

EYE PROTECTION: Use of safety goggles or face shield.

VENTILATION: Not available.

SKIN PROTECTION: Protective clothing.

OTHER PROTECTIVE EQUIPMENT: Not available.

ADDITIONAL EXPOSURE PRECAUTIONS: Not available.

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|-----------------------------|-----------------|-----------------------------|----------------|
| PHYSICAL STATE: | Liquid. | SPECIFIC GRAVITY: | Not available. |
| APPEARANCE AND ODOR: | Clear/ No odor. | EVAPORATION RATE: | Not available. |
| BOILING POINT: | Not available. | MELTING POINT: | Not available. |
| VAPOR PRESSURE: | Not available. | SOLUBILITY IN WATER: | Yes. |
| VAPOR DENSITY: | Not available. | pH: | 4.5-7 |

10. STABILITY AND REACTIVITY

STABILITY: Stable under recommended storage conditions.

INCOMPATIBILITY : (MATERIALS TO AVOID) Oxidizers, acids, bases.

HAZARDOUS POLYMERIZATION: Not available

HAZARDOUS DECOMPOSITION: Not available.

CONDITIONS TO AVOID: Not available.

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11. TOXICOLOGICAL INFORMATION

| ACUTE TOXICITY | | | | |
|----------------|------------------|-------|---------|----------|
| COMPONENT | TYPE | ROUTE | SPECIES | DOSAGE |
| Medetomidine | LD ₅₀ | Oral | Rat | 31 mg/kg |

12. ECOLOGICAL INFORMATION

Not available.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: Dispose of waste in accordance with federal and state regulations.

14. TRANSPORT INFORMATION

REGULATORY ORGANIZATIONS:

DOT: Not Regulated

ICAO / IATA: Not Regulated

IMO: Not Regulated

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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

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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