

# Dexmedetomidine hydrochloride Injection

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : Dexmedetomidine hydrochloride Injection  
Other means of identification : NDC 55150-209-02

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

#### 1.3. Details of the supplier of the safety data sheet

AuroMedics  
6 Wheelling Road  
Dayton, NJ 08810  
T 609-642-1136

#### 1.4. Emergency telephone number

Emergency number : 888-238-7880, option 2

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

##### Classification (GHS-US)

Not classified

#### 2.2. Label elements

##### GHS-US labeling

No labeling applicable

#### 2.3. Other hazards

No additional information available

#### 2.4. Unknown acute toxicity (GHS US)

Not applicable

### SECTION 3: Composition/information on ingredients

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
(+)-4-(S)-[1-(2,3-Dimethylphenyl)ethyl]-1H-imidazole hydrochloride	(CAS No) 145108-58-3	0.1	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335

Full text of classification categories and H statements : see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures after inhalation : If not breathing, give artificial respiration.  
First-aid measures after skin contact : Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention.  
First-aid measures after eye contact : Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention.  
First-aid measures after ingestion : Seek medical attention.

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

Symptoms/injuries after inhalation : None anticipated from normal product handling.  
Symptoms/injuries after skin contact : None anticipated from normal product handling.  
Symptoms/injuries after eye contact : None anticipated from normal product handling.  
Symptoms/injuries after ingestion : None anticipated from normal product handling.

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### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.  
Unsuitable extinguishing media : None.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

### 5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

#### 6.1.1. For non-emergency personnel

No additional information available

#### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.  
Methods for cleaning up : Recycle product or dispose safely.

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : No special handling needed.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : No special storage needed.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

**(+)-4-(S)-[1-(2,3-Dimethylphenyl)ethyl]-1H-imidazole hydrochloride (145108-58-3)**

Not applicable

### 8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.  
Hand protection : If skin contact with the product solution is likely, the use of latex or nitrile gloves is recommended.  
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 and body protection : Wear suitable working clothes.  
Respiratory protection : Respiratory protection is normally not needed during intended product use.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Liquid  
Appearance : Clear.  
Color : Colorless

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Odor	: Odorless
Odor threshold	: No data available
pH	: 4.5 - 7
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: 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
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

### 10.3. Possibility of hazardous reactions

Will not occur.

### 10.4. Conditions to avoid

None.

### 10.5. Incompatible materials

Not determined

### 10.6. Hazardous decomposition products

Not determined

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

#### (+)-4-(S)-[1-(2,3-Dimethylphenyl)ethyl]-1H-imidazole hydrochloride (145108-58-3)

ATE US (oral)	500.000 mg/kg body weight
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Skin corrosion/irritation : Not classified

pH: 4.5 - 7

Serious eye damage/irritation : Not classified

pH: 4.5 - 7

Respiratory or skin sensitization : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

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Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

### SECTION 12: Ecological information

#### 12.1. Toxicity

No additional information available

#### 12.2. Persistence and degradability

No additional information available

#### 12.3. Bioaccumulative potential

No additional information available

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Other adverse effects

Effect on the global warming : No known effects from this product.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

### SECTION 14: Transport information

#### Department of Transportation (DOT)

In accordance with DOT

Not applicable

### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

No additional information available

#### 15.2. US State regulations

No additional information available

### SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation

*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*