

# Dexmedetomidine Hydrochloride Injection

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : Dexmedetomidine Hydrochloride Injection  
Other means of identification : 2 mL single-dose vials packaged in Cartons of 25 Vials NDC 55150-209-02  
50 mL Single Dose Flexible Containers packaged in a Carton of 10 NDC 55150-296-10  
100 mL Single Dose Flexible Containers packaged in a Carton of 10 NDC 55150-297-10

#### 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  
279 Princeton Highstown Road  
East Windsor, NJ 08520

#### 1.4. Emergency telephone number

Emergency number : 1-888-238-7880

### SECTION 2: Hazard(s) identification

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

##### GHS US classification

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. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	%	GHS US classification
Water	(CAS-No.) 7732-18-5	< 99	Not classified
Sodium chloride	(CAS-No.) 7647-14-5	< 1	Not classified
(+)-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 hazard classes and H-statements : see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures after inhalation : Remove to fresh air and keep patient at rest. Seek medical attention immediately.  
First-aid measures after skin contact : Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.  
First-aid measures after eye contact : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.  
First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

Symptoms/injuries after inhalation : None anticipated during normal product use.

# Dexmedetomidine Hydrochloride Injection

## Safety Data Sheet

Symptoms/injuries after skin contact : May cause skin irritation.  
Symptoms/injuries after eye contact : May cause eye irritation.  
Symptoms/injuries after ingestion : May be harmful if swallowed.

### 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 : During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 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 : Absorb spillage with suitable absorbent material. Place in a suitable container and dispose according to local, state and federal regulations.

### 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 : Avoid prolonged and repeated contact. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

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

Storage conditions : Store at 20° to 25°C (68° to 77°F).

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Water (7732-18-5)

Not applicable

#### Sodium chloride (7647-14-5)

Not applicable

#### (+)-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 : No protection is ordinarily required under normal conditions of use.  
Eye protection : Wear safety glasses or goggles.

# Dexmedetomidine Hydrochloride Injection

## Safety Data Sheet

Skin and body protection : Wear suitable working clothes.  
Respiratory protection : No protection is ordinarily required under normal conditions of use.

### SECTION 9: Physical and chemical properties

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

Physical state : Liquid  
Appearance : Clear.  
Color : Colorless  
Odor : Odorless  
Odor threshold : No data available  
pH : No data available  
Melting point : No data available  
Freezing point : No data available  
Boiling point : No data available  
Flash point : Not flammable  
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 : Soluble  
Partition coefficient n-octanol/water (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

Air contact.

#### 10.5. Incompatible materials

None known.

#### 10.6. Hazardous decomposition products

None known.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity : Not classified

##### Water (7732-18-5)

LD50 oral rat : > 90 ml/kg

# Dexmedetomidine Hydrochloride Injection

## Safety Data Sheet

<b>Sodium chloride (7647-14-5)</b>	
LD50 oral rat	3 g/kg
LC50 Inhalation - Rat	> 42 g/m <sup>3</sup> (Exposure time: 1 h)
ATE US (oral)	3000000 mg/kg
<b>(+)-4-(S)-[1-(2,3-Dimethylphenyl)ethyl]-1H-imidazole hydrochloride (145108-58-3)</b>	
ATE US (oral)	500 mg/kg body weight
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

<b>Sodium chloride (7647-14-5)</b>	
LC50 - Fish [1]	5560 – 6080 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 - Fish [2]	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 - Crustacea [2]	340.7 – 469.2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

<b>Sodium chloride (7647-14-5)</b>	
BCF - Fish [1]	(no bioaccumulation)

### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product/Packaging 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

<b>Water (7732-18-5)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory

# Dexmedetomidine Hydrochloride Injection

## Safety Data Sheet

### Sodium chloride (7647-14-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

### 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, Respiratory tract irritation
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.*