

# Ondansetron Injection USP 2 mg/mL

## Safety Data Sheet

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product name : Ondansetron Injection USP 2 mg/mL  
Other means of identification : NDC 55150-125-02 (4 mg/2 mL 25s), NDC 55150-126-20 (40 mg/20 mL 1s)

#### 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: Hazards 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)
Ondansetron hydrochloride	(CAS No) 99614-01-4	< 1	Acute Tox. 3 (Oral), H301

Full text of H-phrases: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures after inhalation : Under normal conditions of intended use, this material is not expected to be an inhalation hazard. No special first aid needed.  
First-aid measures after skin contact : Wash contact areas with soap and water.  
First-aid measures after eye contact : Rinse with water. Get medical attention if irritation develops and persists.  
First-aid measures after ingestion : Rinse mouth thoroughly. No harmful effects expected in amounts likely to be ingested by accident.

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

Symptoms/injuries after inhalation : Under normal conditions of intended use, this material is not expected to be an inhalation hazard.  
Symptoms/injuries after skin contact : Prolonged skin contact may cause irritation.  
Symptoms/injuries after eye contact : Direct contact with eyes may cause temporary irritation.  
Symptoms/injuries after ingestion : May cause discomfort if swallowed.

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

No additional information available

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### 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 : 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 : 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 : Keep container tightly closed.

#### 7.3. Specific end use(s)

No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

Ondansetron hydrochloride (99614-01-4)	
ACGIH	Not applicable
OSHA	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 : No protection is ordinarily required under normal conditions of use.  
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

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Odor	: odorless
Odor threshold	: No data available
pH	: 3.3 - 4
Melting point	: No data available
Freezing point	: No data available
Boiling point	: 100 °C (212 °F)
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Vapor pressure	: No data available
Relative density	: 1 - 1.025 Approx. (15°C)
Relative vapor density at 20 °C	: No data available
Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: 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

Excessive heat. Freezing.

### 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

Ondansetron hydrochloride (99614-01-4)	
LD50 oral rat	94897 µg/kg
ATE US (oral)	94.897 mg/kg body weight

Skin corrosion/irritation : Not classified  
pH: 3.3 - 4

Serious eye damage/irritation : Not classified  
pH: 3.3 - 4

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Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
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 ecological damage caused by 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 a dangerous good as defined in transport regulations

### 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. 3 (Oral)	Acute toxicity (oral) Category 3
H301	Toxic if swallowed

*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*