

Palonosetron Hydrochloride Injection USP

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Palonosetron Hydrochloride Injection USP :
Other means of identification : 5 mL single dose vials (NDC 55150-186-05)

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	> 95	Not classified
D-Mannitol	(CAS No) 69-65-8	1 - 5	Not classified
Palonestron Hydrochloride	(CAS No) 135729-62-3	< 0.1	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332

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 : If not breathing, give artificial respiration. Seek immediate medical attention.
First-aid measures after skin contact : Wash skin with soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
First-aid measures after eye contact : Flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
First-aid measures after ingestion : If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed by medical personnel.

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

Symptoms/injuries after inhalation : None anticipated under normal product handling.
Symptoms/injuries after skin contact : May cause severe burning and skin hyperpigmentation.
Symptoms/injuries after eye contact : May cause eye irritation.
Symptoms/injuries after ingestion : May be harmful if swallowed.

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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 alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray.
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 : Firefighters should wear full protective gear.

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 spill with inert material, then place in a chemical waste container. Dispose in accordance with federal, state and local requirements.

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 all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at controlled room temperature 20-25 C (68-77 F). Protect from light and excessive heat.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Water (7732-18-5)

Not applicable

D-Mannitol (69-65-8)

Not applicable

Palonosetron Hydrochloride (135729-62-3)

Not applicable

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection : Use chemical resistant gloves to minimize skin contact.
Eye protection : Chemical splash goggles. Wear a face shield if a splash hazard exists.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear
Color	: None
Odor	: Odorless
Odor threshold	: No data available
pH	: 4.5-5.5
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

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
D-Mannitol (69-65-8)	
LD50 oral rat	13500 mg/kg
ATE US (oral)	13500 mg/kg

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ATE US (oral)	500 mg/kg body weight
ATE US (dermal)	1100 mg/kg body weight
ATE US (gases)	4500 ppmV/4h
ATE US (vapors)	11 mg/l/4h
ATE US (dust, mist)	1.5 mg/l/4h

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
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

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 regulated for transport

SECTION 15: Regulatory information

15.1. US Federal regulations

Water (7732-18-5)

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

D-Mannitol (69-65-8)

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

15.2. US State regulations

No additional information available

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SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
H302	Harmful if swallowed
H312	Harmful in contact with skin
H332	Harmful if inhaled

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