



Safety Data Sheet

Product Identifier

SECTION 1. IDENTIFICATION

Product Identifier: Granisetron Hydrochloride Injection.

Other Means of Identification: Code L0010140 (1mL), L0010145 (1mL) and L0010141 (4mL).
DIN 02322765

Recommended Use: N/A

Restrictions on Use: N/A

Initial Supplier Identifier: Omega Laboratories, Ltd.
11177 Hamon St.
Montreal, Canada H3M 3E4

Emergency Telephone Number: (514) 335-0310

SECTION 2. HAZARD IDENTIFICATION

Classification: N/A

Label Elements: N/A

Other Hazards: N/A

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	Concentration	Common name / Synonyms	Other identifiers
Granisetron hydrochloride	107007-99-8	0.1%	N/A	N/A
Benzyl alcohol	100-51-6	1.0%	N/A	N/A
Sodium chloride	1310-73-2	0.9%	N/A	N/A
Citric Acid Monohydrate	5949-29-1	0.2%	N/A	N/A
Water for injection	7732-18-5	q.s.	N/A	N/A

Notes

SECTION 4. FIRST-AID MEASURES

Inhalation: If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.

Skin Contact: Wash contaminated skin with soap and water. Get medical attention if irritation develops.

Eye Contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician



immediately.

Most Important Symptoms and Effects, Acute and Delayed: N/A

Immediate Medical Attention and Special Treatment: N/A

SECTION 5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Use water or ABC aqueous-based multi-purpose extinguisher.

Unsuitable Extinguishing Media: N/A

Specific Hazards Arising from the Product: N/A

Special Protective Equipment and Precautions for Fire-Fighters: Move containers from fire area if it can be done without risk to personnel. Incipient fire responders should wear eye protection.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures: Use chemical resistant, impervious gloves, safety glasses and work uniform or laboratory coat. Additional body garments should be used based upon the task being performed. If exposure levels exceed regulatory limits, wear respiratory protection that is in compliance with OSHA 29 CFR1910.134 or equivalent regulation in other regions.

Methods for Containment and Cleaning Up: For small releases, absorb spilled liquid with paper towels or damp sponge. Wash contaminated area with soap and water, absorb with paper towels, and rinse with water. For larger or non-incident spills, absorb spilled liquid with polypads or other suitable absorbent materials. Decontaminate the area thoroughly.

SECTION 7. HANDLING AND STORAGE

Precautions for Safe Handling and conditions for Safe Storage: Store single-use at 15-30°C. Once multi-use vial is penetrated, its contents should be used within 30 days. Do not freeze. Protect from light. Retain in carton until time of use. Do not use discolored solutions.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Chemical Name	ACGIH® TLV®		OSHA PEL	
	TWA	STEL	TWA	STEL
N/A				
N/A				
N/A				

Notes

Appropriate Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures.



Individual Protection Measures

Eye/Face Protection: Safety glasses.

Skin Protection: Use chemical resistant, impervious gloves and work uniform or laboratory coat. Additional body garments should be used based upon the task being performed.

Respiratory Protection: If exposure levels exceed regulatory limits, wear respiratory protection that is in compliance with OSHA 29 CFR1910.134 or equivalent regulation in other regions.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear and colorless.

Odour: Odorless.

Odour Threshold: N/A

pH: 4.0 to 6.0

Melting Point and Freezing Point: N/A

Initial Boiling Point and Boiling Range: 100°C.

Flash Point: N/A

Evaporation Rate: Water (approx.).

Flammability (solid, gas): N/A

Upper and Lower Flammability or Explosive Limit: N/A

Vapour Pressure: N/A

Vapour Density (air = 1): N/A

Relative Density (water = 1): N/A

Solubility in Water: Soluble.

Solubility in Other Liquids: N/A

Partition Coefficient, n-Octanol / Water (Log Kow): N/A

Auto-ignition Temperature: N/A

Decomposition Temperature: N/A

Viscosity: N/A

SECTION 10. STABILITY AND REACTIVITY

Reactivity

Chemical Stability: Stable.

Possibility of Hazardous Reactions: Will not occur.

Conditions to Avoid: Protect from light.

Incompatible Materials: Strong oxidizers, strong acids, some metals and substances incompatible with water.

Hazardous Decomposition Products: Oxides of carbon and nitrogen and hydrogen chloride.

SECTION 11. TOXICOLOGICAL INFORMATION

Likely Routes of Exposure

Inhalation Skin contact Eye contact Ingestion

**Acute Toxicity**

LD50 (oral): Rat 350 mg/kg and mouse 350 mg/kg.

LD50 (Intravenous): Rat 14 mg/kg and mouse 17 mg/kg.

Notes

Skin Corrosion / Irritation: None know.

Serious Eye Damage / Irritation: None know.

STOT (Specific Target Organ Toxicity) - Single Exposure

Ingestion: Diarrhea/constipation. Nervous system effects. (headache, dizziness, light headedness).

Drowsiness. May cause allergic reaction. Harmful if swallowed.

STOT (Specific Target Organ Toxicity) - Repeated Exposure

Respiratory: Inhalation not likely under normal use condition.

Carcinogenicity

Chemical Name	IARC	ACGIH®	OSHA
N/A			
N/A			
N/A			

Notes**Reproductive Toxicity**

Development of Offspring: N/A

Sexual Function and Fertility: N/A

Effects on or via Lactation: N/A

Germ Cell Mutagenicity: N/A

Interactive Effects: N/A

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity**

Persistence and Degradability: N/A

Bioaccumulative Potential: N/A

Mobility in Soil: N/A

Other Adverse Effects: N/A

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal Methods: Place all spill residues in a suitable container and seal. Dispose of in accordance with federal, provincial and local hazardous waste disposal regulations.



SECTION 14. TRANSPORT INFORMATION

Regulation	UN No.	Proper Shipping Name	Technical Name (for N.O.S. entry)	Transport Hazard Class(es)	Packing Group

Special Precautions: N/A

Environmental Hazards: N/A

Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: N/A

SECTION 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations: N/A

SECTION 16. OTHER INFORMATION

Date of Latest Revision

12-06-2019

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