



Safety Data Sheet

Product Identifier

SECTION 1. IDENTIFICATION

Product Identifier: Glycopyrrolate Injection Multidose.

Other Means of Identification: Code L0010203 (20mL) and DIN 02382849.

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
Glycopyrrolate	596-51-0	0.02%	N/A	N/A
Benzyl Alcohol	100-51-6	0.9%	N/A	N/A
Sodium Chloride	7647-14-5	0.85%	N/A	N/A
Sodium Hydroxide	1310-73-2	N/A	N/A	N/A
Hydrochloric Acid	7647-01-0	N/A	N/A	N/A
Water for injection	7732-18-5	q.s.	N/A	N/A

Notes

SECTION 4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. Remove contaminated clothing. Seek medical attention.

Skin Contact: Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.

Eye Contact: Flush for 15 minutes with copious quantities of water. Seek medical attention.

Ingestion: Flush mouth out with water. Seek medical attention.

Most Important Symptoms and Effects, Acute and Delayed: Exposure to this product may result in dry mouth, dizziness, blurred vision and weakness.

Immediate Medical Attention and Special Treatment: N/A



SECTION 5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Water spray, foam, dry chemical or carbon dioxide.

Unsuitable Extinguishing Media: N/A

Specific Hazards Arising from the Product: N/A

Special Protective Equipment and Precautions for Fire-Fighters: Thermally decomposes to form toxic vapors. Vapors may be irritating to eyes and skin and toxic to respiratory tract. Firefighters should wear a self-contained breathing apparatus and full turn out gear. Cool containers with water spray and use caution when approaching.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures: When administering this product to patients, wear nitrile or latex gloves. Use Tyvek SL or equivalent coveralls, PVC booties and nitrile gloves for clean-up activities. Wear ANSI approved chemical splash goggles or safety glasses. Under normal conditions of product use, respiratory protection is not required. When required, use a NIOSH approved air purifying respirator with combination P-100/organic vapor/acid gas cartridges.

Methods for Containment and Cleaning Up: Absorb liquid with suitable material and clean affected area with soap and water. If aerosolized, reduce exposures by ventilating area. Clean up immediately to prevent evaporation. Wear respiratory protection as necessary.

SECTION 7. HANDLING AND STORAGE

Precautions for Safe Handling and conditions for Safe Storage: Protect from light, avoid excessive heat, protect from freezing. Store at 15-30°C. Follow instructions provided in packaging.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

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

Appropriate Engineering Controls: Local exhaust or general ventilation is recommended.

Individual Protection Measures

Eye/Face Protection: Wear ANSI approved chemical splash goggles or safety glasses.

Skin Protection: When administering this product to patients, wear nitrile or latex gloves. Use Tyvek SL or equivalent coveralls, PVC booties and nitrile gloves for clean-up activities.

Respiratory Protection: Under normal conditions of product use, respiratory protection is not required. When required, use a NIOSH approved air purifying respirator with combination P-100/organic vapor/acid gas cartridges.



SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, colorless non-viscous liquid.

Odour: Odorless or slight odor of alcohol.

Odour Threshold: N/A

pH: 2.0-3.0

Melting Point and Freezing Point: N/A

Initial Boiling Point and Boiling Range: Water (approx.).

Flash Point: N/A

Evaporation Rate: Water (approx.).

Flammability (solid, gas): N/A

Upper and Lower Flammability or Explosive Limit: N/A

Vapour Pressure: Water (approx.).

Vapour Density (air = 1): Water (approx.).

Relative Density (water = 1): Water (approx.).

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: Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors.

Incompatible Materials: Reactive with acids, alkalis, oxidizers and metals.

Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, halogenated compounds and nitrogen oxides may be released by thermal decomposition.

SECTION 11. TOXICOLOGICAL INFORMATION

Likely Routes of Exposure

Inhalation Skin contact Eye contact Ingestion

Acute Toxicity

LD50 (IV): Mouse 15 mg/kg.

LD50 (oral): Rat 709 mg/kg, mouse 570 mg/kg and 2360 mg/kg.

LD50 (IP): Mouse 90 mg/kg and rat 196 mg/kg.

Notes



Skin Corrosion / Irritation: Cause irritation to the skin. Product absorbed through the skin.

Serious Eye Damage / Irritation: Cause irritation.

STOT (Specific Target Organ Toxicity) - Single Exposure

Ingestion: May cause irritation, nausea and constipation.

STOT (Specific Target Organ Toxicity) - Repeated Exposure

Respiratory: May cause irritation of respiratory tract. Difficult breathing is possible with inhalation exposure.

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: Refer to local, provincial and federal rules. For the release of water, refer to local water authority. Drain disposal is not recommended; refer to local, state and federal rules.

SECTION 14. TRANSPORT INFORMATION

Regulation	UN No.	Proper Name	Shipping	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

17-06-2019

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