



Material Safety Data Sheet

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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name: Glycopyrrolate Injection, USP

Product code: 0143-9682-25;
0143-9681-25;
0143-9680-25
0143-9679-10

Synonyms: Robinul

Chemical Family: Anticholinergic Agent.

Product Type: Regulated Prescription Drug

Container Information: 1 and 2 mL single dose vials or 5 and 20 mL multiple dose vials

Product Use: Pharmaceutical

Supplier:

WEST-WARD PHARMACEUTICALS
EATONTOWN, NJ 07724

Emergency telephone number: CHEMTREC: USA & Canada (800) 424-9300 OUTSIDE USA +1 703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Glycopyrrolate 596-51-0	0.02	None	None
Benzyl Alcohol 100-51-6	<1	UN1986 (flammable, toxic); UN1987 (alcohol); UN3065 (alcoholic beverages)	Xn;R20/22
Water 7732-18-5	>99	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: Irritation potential to skin, eyes, and mucous membranes. Do not ingest. Avoid skin contact. Avoid eye contact. Wash thoroughly after handling.

Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.

Inhalation: Inhalation not likely under normal use conditions. May cause respiratory tract irritation.

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3. HAZARDS IDENTIFICATION

Ingestion:	Gastrointestinal effects (may include nausea, upset stomach, loss of appetite). Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Nervous system effects (may include drowsiness, confusion, hallucinations, convulsions, visual disturbances, headache, coma). May irritate digestive tract.
Skin contact:	May cause irritation and/or allergic reactions.
Eye contact:	Irritating to eyes.

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:	In case of contact, immediately flush skin with plenty of water. 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.
Eye contact:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.
Notes to physician:	See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Use foam or all purpose dry chemicals to extinguish.
Special protective equipment for firefighters:	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
Specific methods:	No information available.
Flash point:	Not determined
Autoignition temperature:	Not available
Flammable limits in air-lower (%):	Not available
Flammable limits in air-upper (%):	Not available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).
Environmental precautions:	No information available.
Methods for cleaning up:	If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

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7. HANDLING AND STORAGE

Handling:

Technical measures/precautions: Wash thoroughly after handling.

Storage:

Technical measures/storage conditions: Keep containers tightly closed in a cool, well-ventilated place. Store at controlled temperatures between 20°C and 25°C (68°F and 77°F).

Incompatible products: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Glycopyrrolate 596-51-0	None	None	None	None	None	None
Benzyl Alcohol 100-51-6	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures: No special containment is required. Provide general or local exhaust ventilation.

Personal protective equipment:

Respiratory protection: Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode.

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat.

Eye protection: Safety glasses with side-shields. Goggles, face shield, or other full-face protection if potential exists for direct exposure to aerosols or splashes.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Appearance: Aqueous solution
Color: Colorless
Odor: Not available.
pH: 2.0 - 3.0
Molecular weight: Not applicable
Boiling point/range: Not available.
Melting point/range: Not available.
Density: Not available.
Vapor pressure: Not available.
Evaporation rate: Not available.
Solubility: Soluble in water.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Partition coefficient (n-octanol/water): Not available.
Viscosity: Not available.
% Volatile by Volume: Not available.

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.
Polymerization: Not applicable
Hazardous decomposition products: Not available.
Materials to avoid: Oxidizing agents.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Glycopyrrolate 596-51-0	Oral LD50 Rat = 709 mg/kg Oral LD50 Mouse = 570 mg/kg Oral LD50 Rabbit = 2360 mg/kg Intravenous LD50 Mouse = 15 mg/kg Intravenous LD50 Rabbit = 29.1 mg/kg Intravenous LD50 Dog = 25 mg/kg Intramuscular LD50 Cat = 283 mg/kg
Benzyl Alcohol 100-51-6	Oral LD50 Rat = 1230 mg/kg Oral LD50 Mouse = 1360 mg/kg Dermal LD50 Rabbit = 2 gm/kg
Water 7732-18-5	Oral LD50 Rat: >50000 mg/kg

Acute toxicity: Signs and symptoms of overexposure to Anticholinergic drugs may include lethargy, drowsiness, coma, confusion, agitation, hallucinations, convulsions, visual disturbances, dry flushed skin, dry mouth, decreased bowel sounds, urinary retention, increased heart rate, high blood pressure, and supraventricular arrhythmias.

Chronic toxicity: Contains material which may cause damage to the following organs: skin, eye, lens or cornea.

Carcinogenic effects: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No data is available on the product itself.

Mutagenic effects: No data is available on the product itself.

Reproductive toxicity: May impair fertility based on animal data. Not considered fetotoxic based on animal data. See patient package insert for additional information.

FDA Pregnancy Category B

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12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Microtox Eotoxicity Data
Glycopyrrolate 596-51-0	None.	None.	None.	None.
Benzyl Alcohol 100-51-6	= 23 mg/L EC50 water flea	LC50 (96 hr) fathead minnow:460 mg/L: Static, 18-22°C; LC50 (96 hr) bluegill:10 mg/L: Static.	None.	= 63.7 mg/L EC50 Photobacterium phosphoreum = 71.4 mg/L EC50 Photobacterium phosphoreum
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name: None
UN Number: None
DOT Packing Group: None
DOT Hazard class: None

TDG (Canada):

TDG Proper shipping name: None
TDG UN/NA Number: None
TDG Packing Group: None
TDG Hazard class: None

ADR/RID:

ADR Official Transport Name: None
ADR Proper shipping name: None
ADR UN/NA number: None
ADR Hazard Class: None

ICAO / IATA:

IATA Proper shipping name: None
IATA UN NUMBER: None
IATA Primary Hazard: None
IATA Packing group: None

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14. TRANSPORT INFORMATION

ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name: None

IMDG Hazard Class and Division: None

IMDG Packing Group: None

IMDG Subsidiary Risks: None

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated

Japanese Inventory (ENCS) This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Glycopyrrolate	0.02	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	<1	Not Listed	Not Listed	Not Listed	Not Listed
Water	>99	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop 65:	Minnesota Right-To - Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Glycopyrrolate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	Not Listed	Present	Not Listed	Not Listed	Present	[present]	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

EU EINECS List - This product complies with EINECS

Risk Phrases:

NONE

Safety Phrases:

NONE

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):

Updated NDC codes

Additional information:

Not Available.

Prepared by: West-Ward Pharmaceuticals

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of safety data sheet

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