

SAFETY DATA SHEETS

This SDS packet was issued with item:

078951755

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078951749 078951750 078951756

SAFETY DATA SHEET



Glycopyrrolate, USP

1) PRODUCT AND COMPANY IDENTIFICATION

Product name:	Glycopyrrolate Injection, USP
Synonyms:	Robinul
CAS Number:	Mixture
Chemical Family:	Anticholinergic Agent
Recommended Use:	Regulated Prescription Drug to be Administered by Medical Professionals
Container Information:	1 and 2 mL single dose vials or 5 and 20mL multiple dose vials
Manufacturer:	Piramal Critical Care, Inc 268 Brodhead Road Bethlehem, PA 18017
Important Phone Numbers:	Customer Service: 610-974-9760 x 510 E-Mail: pcccustomerconnect@piramal.com 24 Hour Emergency: 484-895-5734
24 Hour Emergency Number:	CHEMTREC 1-800-424-9300 (For Transportation in US and Canada)

2) HAZARDS IDENTIFICATION

OSHA/HCS Status:	While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.
Classification:	Not classified
<u>GHS Label Elements</u>	
Signal Word:	No signal word
Hazard Statements:	No known significant effects or critical hazards

Precautionary Statements

Prevention: Not applicable
Response: Not applicable
Storage: Not applicable
Dispose: Not applicable

**Hazard(s) Not
Otherwise Classified (HNOC):** None Known

3) COMPOSITION/INFORMATION ON INGREDIENTS

<u>Chemical Name</u>	<u>CAS Number</u>	<u>%</u>
Water	7732-18-5	60-100
Benzyl alcohol	100-51-6	0.1-1
Glycopyrrolate	596-51-0	0-0.1

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

4) FIRST AID MEASURES

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

Skin Contact: Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.

Eye Contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Ingestion: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Symptoms/Effects: There are no known significant effects or critical hazards associated with acute and delayed exposure (acute and over-exposure)

Note to Physician:	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific Treatments:	No specific treatment.
Protection of first-aiders:	No action shall be taken involving any personal risk or without suitable training.

5) FIRE FIGHTING MEASURES

Suitable Extinguishing Media:	Use media suitable for the surrounding fire(s).
Unsuitable Extinguishing Media:	None known
Specific Hazards Arising from the Chemical:	No specific fire or explosion hazard.
Hazardous thermal Decomposition products:	No specific data
Special protective actions for fire-fighters:	No special protection is required.
Special protective equipment for fire-fighters:	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece oriented in positive pressure mode.

6) ACCIDENTAL RELEASE MEASURES

In Case of Spill or Leak:	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.
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Personal Precautions

Non-emergency Personnel:	No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering Do not touch or walk through spilled material. Put on appropriate personal protective equipment.
For Emergency Responders:	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel"

Environmental Precautions: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform relevant authorities if the product has caused environmental pollution (sewers, waterways, soil, or air).

7) HANDLING AND STORAGE

Precautions for Safe Handling

Protective Measures: Put on appropriate personal protective equipment (see Section 8).

Advice on general Occupational hygiene: Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

Storage: Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

8) EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

Environmental Exposure Controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual Protection Measures

Hygiene Measures: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye Protection: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side- shields.

Hand Protection:	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
Body Protection:	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Skin Protection:	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product..
Respiratory Protection:	Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of
Occupational Exposure Limits:	None

9) PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear
Physical State:	Liquid
Color:	Colorless
Odor:	Not available
Odor Threshold:	Not available
pH:	2-3
Boiling Point:	Not available
Melting:	Not available
Vapor Pressure:	Not available
Vapor Density:	Not available
Relative Density:	Not available
Evaporation Rate:	Not available
Water Solubility:	Not available
Specific Gravity:	Not available
Flash Point:	N/A
Burning Time:	N/A
Burning Rate:	N/A
Explosive Limits:	Not available
Ignition Temperature:	Not available
Decomposition Temperature:	Not available
SADT:	Not available
Flammability (solid/gas):	Not available
Partition coefficient:	Not available

Solubility: Easily soluble in the following materials: cold water and hot water
Water Solubility: Not available
Viscosity: Not available

10) STABILITY AND REACTIVITY

Chemical Stability: This product is stable
Incompatibility: Reactive or incompatible with the following materials: oxidizing materials.
Polymerization: Not available
Hazardous Decomposition Products: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to Avoid: No specific data.
Reactivity: No specific test data related to reactivity available for this product or its ingredients.

11) TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute Toxicity: There is no data available

Irritation / Corrosion: There is no data available

Sensitization: There is no data available

Mutagenicity: There is no data available

Carcinogenicity: There is no data available

Reproductive Toxicity: There is no data available

Teratogenicity: There is no data available

Specific Target Organ Toxicity (Single Exposure) : There is no data available

Specific Target Organ Toxicity (Repeated Exposure) : There is no data available

Aspiration Hazard: There is no data available

**Information on the likely
routes of exposure:**

Dermal contact. Eye Contact. Inhalation. Ingestion

Potential Acute Health Effects

Eye Contact	No known significant effects or critical hazards
Inhalation	No known significant effects or critical hazards
Skin Contact	No known significant effects or critical hazards
Ingestion	No known significant effects or critical hazards

Symptoms related to the physical, chemical, and toxicological characteristics

Eye Contact	No known significant effects or critical hazards
Inhalation	No known significant effects or critical hazards
Skin Contact	No known significant effects or critical hazards
Ingestion	No known significant effects or critical hazards

Delayed and Immediate effects and also chronic effects from short and long term exposure**Short Term and Long Term Exposure**

Potential Immediate Effects	No known significant effects or critical hazards
Potential Delayed Effects	No known significant effects or critical hazards

Potential Chronic Health Effects

General	No known significant effects or critical hazards
Carcinogenicity	No known significant effects or critical hazards
Mutagenicity	No known significant effects or critical hazards
Teratogenicity	No known significant effects or critical hazards
Developmental Effects	No known significant effects or critical hazards
Fertility Effects	No known significant effects or critical hazards

Numerical measures of toxicity

Acute toxicity measurements: There is no data available

Other Information: FDA Class B

12) ECOLOGICAL INFORMATION

Toxicity:	No data available
Bioaccumulation:	No data available
Degradability and Persistence:	No data available
Mobility in Soil:	No data available
Other adverse effects:	No known significant effects or critical hazards

13) DISPOSAL CONSIDERATIONS**Disposal Instructions:**

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

14) TRANSPORT INFORMATION**DOT:**

Not regulated as dangerous goods

IATA:

Not regulated as dangerous goods

IMDG:

Not regulated as dangerous goods

Environmental Hazards:

No

AERG:

Not available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:

Not available

Special Precautions for user:

Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

15) REGULATORY INFORMATION**US Federal Regulations:**

TSCA 8(a) CDR Exempt/Partial Exemption: Not Determined
United States Inventory (TSCA 8b): Not Determined

CERCLA (Superfund) Reportable Quantity – Not applicable

SARA 304 Emergency Release Notification – No products found

SARA 302 Extremely Hazardous Substance – No products found

SARA 311/312 Hazardous Chemical – Not Applicable / No products found

Other Federal Regulations:

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List – Not Listed

Clean Air Act (CAA) Section 602 Class I Substances – Not Listed

Clean Air Act (CAA) Section 602 Class II Substances – Not Listed

DEA List I Chemicals (Precursor Chemicals) – Not Listed

DEA List II Chemicals (Essential Chemicals) – Not Listed

Federal Food and Drug Administration (FDA) - Regulated

US State Regulations:

US Massachusetts – None of the components listed

US New Jersey – None of the components listed

US Pennsylvania None of the components listed

US New York – None of the components listed

US California Proposition 65 – No products found

International Inventories:

Country/Region	Inventory Name	On Inventory*
Australia	Australian Inventory of Chemical Substances (AICS)	All components are listed or exempted
China	Inventory of Existing Chemical Substances in China (IECSC)	Not determined
Japan	Inventory of Existing and New Chemical Substances (ENCs)	Not determined
Korea	Existing Chemicals List (ECL)	Not determined
New Zealand	New Zealand Inventory	Not determined
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Not determined
Taiwan	Taiwan Inventory (CSNN)	Not determined
Malaysia	Malaysia Inventory (EHS Register)	Not determined

Chemical Weapons Convention List Schedule I Chemicals: Not Listed

Chemical Weapons Convention List Schedule II Chemicals: Not Listed

Chemical Weapons Convention List Schedule III Chemicals: Not Listed

16) OTHER INFORMATION

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SDS Updates:

04-11-2019 – New Document