

# SAFETY DATA SHEET



## Glycopyrrolate, USP

### 1) PRODUCT AND COMPANY IDENTIFICATION

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

### 2) HAZARDS IDENTIFICATION

<b>OSHA/HCS Status:</b>	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.
<b>Classification:</b>	Not classified
<b><u>GHS Label Elements</u></b>	
<b>Signal Word:</b>	No signal word
<b>Hazard Statements:</b>	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)

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

## **5) FIRE FIGHTING MEASURES**

<b>Suitable Extinguishing Media:</b>	Use media suitable for the surrounding fire(s).
<b>Unsuitable Extinguishing Media:</b>	None known
<b>Specific Hazards Arising from the Chemical:</b>	No specific fire or explosion hazard.
<b>Hazardous thermal Decomposition products:</b>	No specific data
<b>Special protective actions for fire-fighters:</b>	No special protection is required.
<b>Special protective equipment for fire-fighters:</b>	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**

<b>In Case of Spill or Leak:</b>	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.
<b><u>Personal Precautions</u></b>	
<b>Non-emergency Personnel:</b>	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.
<b>For Emergency Responders:</b>	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.

<b>Hand Protection:</b>	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.
<b>Body Protection:</b>	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.
<b>Skin Protection:</b>	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..
<b>Respiratory Protection:</b>	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
<b>Occupational Exposure Limits:</b>	None

## **9) PHYSICAL AND CHEMICAL PROPERTIES**

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

<b>Eye Contact</b>	No known significant effects or critical hazards
<b>Inhalation</b>	No known significant effects or critical hazards
<b>Skin Contact</b>	No known significant effects or critical hazards
<b>Ingestion</b>	No known significant effects or critical hazards

**Symptoms related to the physical, chemical, and toxicological characteristics**

<b>Eye Contact</b>	No known significant effects or critical hazards
<b>Inhalation</b>	No known significant effects or critical hazards
<b>Skin Contact</b>	No known significant effects or critical hazards
<b>Ingestion</b>	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**

<b>Potential Immediate Effects</b>	No known significant effects or critical hazards
<b>Potential Delayed Effects</b>	No known significant effects or critical hazards

**Potential Chronic Health Effects**

<b>General</b>	No known significant effects or critical hazards
<b>Carcinogenicity</b>	No known significant effects or critical hazards
<b>Mutagenicity</b>	No known significant effects or critical hazards
<b>Teratogenicity</b>	No known significant effects or critical hazards
<b>Developmental Effects</b>	No known significant effects or critical hazards
<b>Fertility Effects</b>	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**

<b>Toxicity:</b>	No data available
<b>Bioaccumulation:</b>	No data available
<b>Degradability and Persistence:</b>	No data available
<b>Mobility in Soil:</b>	No data available
<b>Other adverse effects:</b>	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:**

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

**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