



## SAFETY DATA SHEET

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Revision Number 00

### 1. IDENTIFICATION

**Product Name** Glycopyrrolate Injection, USP (0.2 mg/mL)

**Type of Container** Vials (0.2 mg/ 1 mL, 0.4 mg/ 2 mL, 1 mg/ 5 mL, 4 mg/20 mL)

**Synonyms** Ascecril, Gastrodyn, Nodapton, Robanul, Robinul, Tarodyl, Tarodyn; 1-Methyl-3-Pyrrolidyl alpha-phenylcyclopentaneglycolate methobromide; Glycopyrrolate bromide; Glycopyrronium bromide

**Recommended Use** Specified quality tests and assay use only.

**Manufacturer Name And Address**

Amneal Pharmaceuticals Pvt. Ltd.  
Plot No.15,PHARMEZ-SEZ, Sarkhej-Bavla Highway,  
Ta. Sanad , Dist. Ahmeddabad-382220, Gujarat, India.

**Emergency Telephone number**

+91-2714-671600

### 2. HAZARDS IDENTIFICATION

**Carcinogen List**

Substance	IARC	NTP	OSHA
Glycopyrrolate	Not Listed	Not Listed	Not Listed

**Emergency Overview** Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

**Hazard Class** Not applicable

**Signal word** Not applicable

**Symbol** Not applicable

**Precautionary Statement** P-260- Do not breathe vapor/dust/gas/mist/fumes/spray

**Hazard Statement** Not applicable

**Product Name:** Glycopyrrolate Injection, USP

<b>Occupational Exposure Potential</b>	Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
<b>Signs and Symptoms</b>	None known from occupational exposures. Adverse effects have included gastrointestinal distress and fever from parenteral administration.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Active Ingredient Name**

**Chemical Formula** C19-H28-Br-N-O3

**Preparation** Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride; sodium hydroxide and/or hydrochloric acid are added to adjust the pH.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Glycopyrrolate	0.2 mg/ml	596-51-0	NA
Benzyl Alcohol	< 1 mg/ml	100-51-6	NA

### 4. FIRST-AID MEASURES

<b>Eye contact</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Skin contact</b>	In case of contact, immediately flush skin with plenty of water. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Inhalation</b>	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.
<b>Ingestion</b>	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. 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.

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## 5. FIRE-FIGHTING MEASURES

<b>Flammability</b>	Not determined
<b>Flash point:</b>	Not determined
<b>Auto ignition Temperature</b>	Not available
<b>Fire &amp; Explosion Hazard</b>	Not available.
<b>Extinguishing media</b>	Use foam or all-purpose dry chemicals to extinguish.
<b>Special Fire Fighting Procedures</b>	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

<b>Personal precautions:</b>	Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all firefighting procedures (Section 5).
<b>Spill Cleanup and Disposal</b>	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

## 7. HANDLING AND STORAGE

<b>Handling</b>	No special handling required under conditions of normal product use.
<b>Storage</b>	No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary Container label, or the product insert.
<b>Special Precautions</b>	No special precautions required for hazard control.
<b>Storage Conditions</b>	Store dry product and reconstituted solution at 20° - 25 °C (68° - 77°F). Protect from light, store in carton until time of use. Follow instructions provided in packaging.

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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Occupational Exposure Limits

Component	OSHA-Time Weighted Average:	OSHA-Short Term Exposur	OSHA-Ceiling Limits	ACGIH-Time Weighted Average:	ACGIH-Short Term Exposur	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.

**Engineering Controls** Engineering controls are normally not needed during the normal use of this product. Handle product in a well-ventilated area.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance/Physical State</b>	Liquid
<b>Color</b>	Colorless aqueous solution.
<b>Odor</b>	NA
<b>Odor Threshold:</b>	NA
<b>pH:</b>	2.0-3.0
<b>Melting point/Freezing point:</b>	NA
<b>Initial Boiling Point/Boiling Point</b>	NA
<b>Range:</b>	
<b>Evaporation Rate:</b>	NA
<b>Flammability (solid, gas):</b>	NA
<b>Upper/Lower Flammability or</b>	NA
<b>Explosive Limits:</b>	
<b>Vapor Pressure:</b>	NA
<b>Vapor Density:</b>	NA
<b>Specific Gravity:</b>	NA
<b>Solubility:</b>	soluble in water
<b>Partition coefficient: n-octanol/water:</b>	NA
<b>Auto-ignition temperature:</b>	NA
<b>Decomposition temperature:</b>	NA

## 10. STABILITY AND REACTIVITY

<b>Stability</b>	Stable under recommended storage conditions.
<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>Hazardous Reactions</b>	Not determined.
<b>Conditions to avoid</b>	Oxidizing agent.
<b>Incompatibilities</b>	Not determined.
<b>Hazardous Polymerization</b>	Not applicable.
<b>Hazardous decomposition products</b>	Not determined.

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## 11. TOXICOLOGICAL INFORMATION

### Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Glycopyrrolate	100	LD50	Oral	709 570 2360	mg/kg mg/kg mg/kg	Rat Mouse Rabbit
Glycopyrrolate	100	LD50	Intravenous	15 29.1	mg/kg mg/kg	Mouse Rabbit
Glycopyrrolate	100	LD50	Intramuscular	283	mg/kg	Cat

### 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	Eco toxicity - Water Flea Data	Fish Species Eco toxicity	Eco toxicity - Freshwater Algae Data	Microtox Etoxicity 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

**Ecotoxicity effects:** No data available

**Bioaccumulation:** No data available

**Mobility in Soil** Not determined for product.

## 13. DISPOSAL CONSIDERATIONS

**Waste Disposal** All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

**Container Handling and Disposal** Dispose of container and unused contents in accordance with federal, state and local regulations.

## 14. TRANSPORT INFORMATION

**ADR/ADG/ DOT STATUS:** Not regulated

**IMDG STATUS:** Not regulated

**ICAO/IATA STATUS:** Not regulated

**Transport Comments:** None

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## 15. REGULATORY INFORMATION

### USA Regulations

Substance	Weight %	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Glycopyrrolate	0.02	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl alcohol	< 1	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

**RCRA Status** Not Listed

**U.S. OSHA** TSCA Inventory List: The product is exempt from TSCA, it is FDA Regulated

**Classification** Possible Irritant

**Hazard Class** Not Applicable

**Hazard Category** Not Applicable

**Signal Word** Not Applicable

**Symbol** Not Applicable

**Prevention** P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

**Hazard Statement** Not applicable

**Response** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell

### EU Classification\*

\*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Glycopyrrolate.

**Classification(s):** Not Applicable

**Symbol:** Not Applicable

**Indication of Danger:** Not Applicable

**Risk Phrases:** Not Applicable

**Safety Phrases:** S23 - Do not breathe vapor.  
S24/25 - Avoid contact with skin and eyes.  
S37/39 - Wear suitable gloves and eye/face protection.

**WHMIS (Canada):** Not controlled under WHMIS (Canada).



## 16. OTHER INFORMATION:

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

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<b>Further information</b>	Not available.

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**Product Name:** Glycopyrrolate Injection, USP