

SAFETY DATA SHEET
PRODUCT: Glycopyrrolate Injection USP

Section 1: PRODUCT AND COMPANY INFORMATION

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| 54/1, Boodhihal village, Nelamangala, Bangalore, India-562123. PRODUCT NAME: Glycopyrrolate Injection USP 0.2 mg/mL |
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Section 2: HAZARDS IDENTIFICATION

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| EMERGENCY OVERVIEW | |
| Appearance/Odor | Clear colorless solution free from visible extraneous matter, filled in clear tubular glass vials plugged with gray rubber stopper and sealed with Navy blue flip off aluminium seals |
| Irritation potential to skin, eyes and mucous membranes. Do not ingest. Avoid skin contact. Avoid eye contact. Wash thoroughly after handling. | |
| Principal routes of exposure | Absorbed through skin. Eye contact. Ingestion |
| <i>Potential Health Effects: See Section 11 for more information</i> | |
| Likely Routes of Exposure | Absorbed through skin. Eye contact. Ingestion |
| Inhalation | Inhalation not likely under normal use conditions. May cause tract irritation. |
| Eye contact | Causes irritation of the eye. |
| Skin contact | Causes irritation and /or allergic reactions. |
| Ingestion | Gastrointestinal effects (may include nausea, upset stomach, and loss of appetite) cardiovascular effects (may include fluctuation in heart rate, changes in blood pressure, chest pain) nervous system effects (may include drowsiness, confusion, hallucinations, convulsion, visual disturbances, headache, and coma). May irritate digestive tract. |
| <i>Potential Environmental Effects: See Section 12 for more information</i> | |

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS

| Component | CAS Number |
|---------------------|------------|
| Glycopyrrolate | 596-51-0 |
| Benzyl Alcohol | 100-51-6 |
| Sodium Hydroxide | 1310-73-2 |
| Hydrochloric Acid | 7647-01-0 |
| Water for Injection | 7732-18-5 |

Section 4: FIRST AID MEASURES

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| Eye Contact | Causes irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention. |
| Skin Contact | May cause irritation. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention if irritation develops. |
| 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. |
| 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 |
| Injection | See prescribing information. |
| Note to Physicians | See patient package insert in shipping carton for complete information |

Section 5: FIRE FIGHTING MEASURES

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| Suitable Extinguishing Media | Water spray, dry chemical, foam, carbon dioxide. |
| Unsuitable Extinguishing Media: | A heavy water stream may spread burning liquid. CAUTION: Carbon dioxide is an asphyxiant. Lack of oxygen can be fatal. |
| Special Hazards Arising From the Substance or Mixture Reactivity: | Hazardous reactions will not occur under normal conditions. |
| Advice for Firefighters Firefighting Instructions: | Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers. |
| Protection During Firefighting: | Firefighters must use full bunker gear including NIOSH-approved positive-pressure self-contained breathing apparatus to protect against potential hazardous combustion and decomposition products. |

Section 6: ACCIDENTAL RELEASE MEASURES

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| Personal Precautions, Protective Equipment and Emergency Procedures General Measures: | Avoid all unnecessary exposure. Do not breathe vapour or mist. |
| For Non-emergency Personnel Protective Equipment: | Use appropriate personal protection equipment (PPE). Refer to section 8 |
| Emergency Procedures: | Evacuate unnecessary personnel. |
| For Emergency Responders Protective Equipment: | Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection". |
| Emergency Procedures: | Ventilate area. |
| Environmental Precautions | Prevent entry to sewers and public waters. |
| Methods and Material for Containment and Cleaning Up Methods for Cleaning Up: | Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water. |

Section 7: HANDLING AND STORAGE

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| Precautions for Safe Handling Hygiene Measures: | Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work. |
| Conditions for Safe Storage, Including Any Incompatibilities Technical Measures: | Comply with applicable regulations. |
| Storage Conditions | Store in a dry, well ventilated place at 20° -25°C (68°- 77°F) away from direct sunlight and incompatible materials. |
| Incompatible Products: | Strong bases. Strong oxidizers. |

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

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| Engineering Controls: | Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit. |
| Personal Protection | Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves. |
| Personal Protection in Case of a Large Spill: | Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid Inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product. |
| Exposure Limits: | Not available. |

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid.
Appearance: Clear colorless solution
Odor: Odorless.
Taste: Not available.
Molecular Weight: 398.33 g/mole
Color: White.
pH (1% soln/water): Not available.
Boiling Point: Not available.
Melting Point: 193°C (379.4°F)
Critical Temperature: Not available.
Specific Gravity: Not available.
Vapor Pressure: Not applicable.
Vapor Density: Not available.
Volatility: Not available.
Odor Threshold: Not available.
Water/Oil Dist. Coeff.: Not available.
Ionicity (in Water): Not available.
Dispersion Properties: See solubility in water.
Solubility: Soluble in cold water.

Section 10: STABILITY AND REACTIVITY

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, dust generation, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents.

Corrosivity: Not available.

Special Remarks on Reactivity: Not available.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: TOXICOLOGY INFORMATION

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 570 mg/kg [Mouse].

Chronic Effects on Humans: Not available.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: May cause adverse reproductive effects based on animal test data

Special Remarks on other Toxic Effects on Humans:

Potential Health Effects: Skin Contact: May cause skin irritation and reddening. Possible allergic reaction. It may be absorbed through intact skin. Eyes: May cause eye irritation. Inhalation: May cause respiratory tract irritation and difficulty in breathing. Possible allergic reaction to dust if inhaled Ingestion: May be harmful if swallowed. May cause gastrointestinal tract irritation with hypermobility, and diarrhoea or constipation. May affect behavior/central nervous system (convulsions, somnolence, dizziness, and slurred speech), respiration (difficulty breathing, dyspnoea), eyes (mydriasis), and metabolism (weight loss). Other adverse effects may include bitter taste, dryness of mouth, nose or throat, warm or flushed skin, severe tiredness or muscle weakness, rapid heartbeat, and rarely, blurred vision. Possible allergic reaction if ingested. Prolonged or repeated ingestion may affect the urinary system (bladder), endocrine system (adrenal gland, thyroid gland), blood.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: Not available.
BOD5 and COD: Not available.
Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.
Toxicity of the Products of Biodegradation: The products of degradation are as toxic as the product itself.
Special Remarks on the Products of Biodegradation: Not available.

Section 13: DISPOSAL CONDITIONS

Waste Disposal: Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: TRANSPORTATION INFORMATION

| Regulatory Agency | Shipping Description |
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| US DOT (ground) | Not considered a DOT regulated material - Non-hazardous for Shipment. |
| Identification: | Not applicable. |
| Special Provisions for Transport: | Not applicable. |

Section 15: REGULATORY INFORMATION

Federal and State Regulations: No products were found.

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

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

DSCL (EEC):

R22- Harmful if swallowed. S2- Keep out of the reach of children. S46- If swallowed, seek medical advice immediately and show this container or label.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 1

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:

Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Safety glasses.

Section 16: OTHER INFORMATION

This information is based on our present state of knowledge. It should not therefore be constructed as guaranteeing specific properties of the products described or their suitability for a particular application.