

## SAFETY DATA SHEET

### SECTION 1 : IDENTIFICATION

**Product Name:** Glycopyrrolate Injection, USP  
**Manufacturer Name:** Fresenius Kabi USA, LLC  
**Address:** Three Corporate Drive  
 Lake Zurich, Illinois 60047  
**General Phone Number:** (847) 550-2300  
**Customer Service Phone Number:** (888) 386-1300  
**Health Issues Information:** (800) 551-7176  
**SDS Creation Date:** February 07, 2018  
**SDS Revision Date:** February 07, 2018

### SECTION 2 : HAZARD(S) IDENTIFICATION

**Signal Word:** Not applicable.  
**Hazard Statements:** Not applicable.  
**Precautionary Statements:** Not applicable.

**Emergency Overview:** This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Avoid contact with skin, eyes, nostrils and mouth.

**Route of Exposure:** Inhalation Ingestion Eye contact Skin Absorption. Injection.

**Eye:** Contact with eyes may cause irritation.

**Skin:** May cause irritation.

**Inhalation:** May cause irritation.

**Ingestion:** May be harmful if ingested.

**Aggravation of Pre-Existing Conditions:** None generally recognized.

### SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Benzyl alcohol	100-51-6	9.0 mg/ mL by weight	
Glycopyrrolate	596-51-0	0.2 mg/ mL by weight	
Hydrochloric Acid/Sodium hydroxide	7647-01-0/1310-73-2	As needed to adjust pH	
Water for Injection	7732-18-5	Balance	

### SECTION 4 : FIRST AID MEASURES

**Eye Contact:** Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

**Skin Contact:** Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

**Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

**Ingestion:** If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

**Other First Aid:** For Adverse Event Information, please call (800) 551-7176.

### SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

## SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

## SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at 20° to 25°C (68° to 77°F).
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site ( <a href="http://www.cdc.gov/niosh/npptl/topics/respirators/">http://www.cdc.gov/niosh/npptl/topics/respirators/</a> ) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

### EXPOSURE GUIDELINES

#### Hydrochloric Acid/Sodium hydroxide :

Guideline ACGIH:	TLV-STEL: 2 ppm (ceiling)
Guideline OSHA:	OSHA PEL-STEL 5 ppm Ceiling/Peak

## SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid.
Color:	Colorless.
Boiling Point:	Not established.
Melting Point:	Not established.

Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	2.0 - 3.0
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

## SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Protect from freezing.
Incompatible Materials:	Incompatible with strong acids and bases.

## SECTION 11 : TOXICOLOGICAL INFORMATION

### Benzyl alcohol :

RTECS Number:	DN3150000
Ingestion:	Oral - LD50 - Rat - 1230 mg/kg

### Glycopyrrolate :

RTECS Number:	UY4337630
Ingestion:	Oral - LD50 - Rat - 709 mg/kg

### Hydrochloric Acid/Sodium hydroxide :

RTECS Number:	MW4025000
Eye:	Eye - Rabbit Total particulate/dust (T): 5 mg/30S (RTECS)
Skin:	Administration onto the skin - Human Standard Draize test.: 4 %/24H (RTECS)
Inhalation:	Inhalation - Rat LC50: 3124 ppm/1H [Sense Organs and Special Senses (Olfaction) - effect, not Otherwise specified Sense Organs and Special Senses (Eye) - Iritis] Inhalation - Mouse LC50: 1108 ppm/1H [Sense Organs and Special Senses (Eye) - effect, not Otherwise specified Lungs, Thorax, or Respiration - Respiratory stimulation Skin and Appendages - Dermatitis, other (After systemic exposure)] Inhalation - Rat LC50: 45000 mg/m <sup>3</sup> /5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50: 8300 mg/m <sup>3</sup> /30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Mouse LC50: 8300 mg/m <sup>3</sup> /30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - LC50: 0.1 gm/m <sup>3</sup> [Details of toxic effects not reported other than lethal dose value] Inhalation - Rat LC50: 60938 mg/m <sup>3</sup> /5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Mouse LC50: 20487 mg/m <sup>3</sup> /5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50: 7004 mg/m <sup>3</sup> /30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Mouse LC50: 3940 mg/m <sup>3</sup> /30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50: 3700 ppm/30M [Details of toxic effects not reported other than lethal dose value] Inhalation - Mouse LC50: 2644 ppm/30M [Details of toxic effects not reported other than lethal dose value] (RTECS)
Ingestion:	Oral - Rabbit LD50: 900 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

## SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

## SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.
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## SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

## SECTION 15 : REGULATORY INFORMATION

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**Hydrochloric Acid/Sodium hydroxide :**

TSCA Inventory Status: Listed  
EINECS Number: 231-595-7  
SARA: EPCRA - 40 CFR Part 372 - (SARA Title III) Section 313 Listed Chemical.  
Section 302 EHS: EPCRA (SARA Title III) Section 302 (40 CFR Part 355) Extremely Hazardous Substances (EHS) Threshold Planning Quantity (TPQ) in pounds.: 500 Lbs.  
Section 304 RQ: EPCRA (SARA Title III) Section 304 Extremely Hazardous Substances (EHS) Reportable Quantities (RQ) in pounds.: 5,000 Lbs.  
Canada DSL: Listed  
Canada IDL: Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.845(502)

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**SECTION 16 : ADDITIONAL INFORMATION**

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**HMIS Ratings:**

HMIS Health Hazard: 1  
HMIS Fire Hazard: 0  
HMIS Reactivity: 0  
HMIS Personal Protection: X

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**Disclaimer:** The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

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