

# MATERIAL SAFETY DATA SHEET

Version No: MSDS/Gly-AUS/DP-003

Effective Date: 08<sup>th</sup> April 2020

## GLYCOPYRRONIUM BROMIDE 200 MICROGRAMS/ML INJECTION

### SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Glycopyrronium Bromide 200 micrograms/mL Injection

#### Intended Use of the Product

**Use of the substance/mixture:** Indicated for use in anesthesia as a preoperative antimuscarinic to reduce salivary, tracheobronchial, and pharyngeal secretions; to reduce the volume and free acidity of gastric secretions; and, to block cardiac vagal inhibitory reflexes during induction of anesthesia and intubation. When indicated, glycopyrrolate injection may be used intraoperatively to counteract surgically or drug-induced or vagal reflexes associated arrhythmias. Glycopyrrolate protects against the peripheral muscarinic effects (e.g., bradycardia and excessive secretions) of cholinergic agents such as neostigmine and pyridostigmine given to reverse the neuromuscular blockade due to non-depolarizing muscle relaxants. For use in adults as adjunctive therapy for the treatment of peptic ulcer when rapid anticholinergic effect is desired or when oral medication is not tolerated.

#### Details of the Supplier of the Safety Data Sheet

**Manufacturer:**

Intas Pharmaceuticals Ltd.  
Plot No. 457, 458  
Village-Matoda,  
Bavla Road, Ta. Sanand,  
Dist. Ahmedabad-382 210,  
Gujarat, India

**Sponsor:**

Accord Healthcare Pty Ltd  
Level 24, 570 Bourke Street,  
Melbourne, VIC, 3000,  
Australia

### SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

Active Ingredient	Product Identifier	%	Classification (GHS-US)
Glycopyrronium bromide (Glycopyrrolate)	(CAS No) 596-51-0	0.02	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2B, H320 STOT SE 3, H335

Inactive Ingredient	Product Identifier	%	Classification (GHS-US)
Sodium chloride	(CAS No) 7647-14-5	*	Not Listed
hydrochloric acid	(CAS No) 7647-01-0	Used to adjust pH	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)
water for injection	(CAS No) 7732-18-5	99.1	Not classified

Full text of H-phrases: see section 16

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## SECTION 3 - HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

**Classification (GHS-US):** Not classified

### Label Elements

**GHS-US Labeling:** No labeling applicable

**Other Hazards:** Refer to patient insert for more information. Exposure may aggravate individuals with pre-existing skin, kidney, liver, and pulmonary disorders.

**Unknown Acute Toxicity (GHS-US):** No data available

## SECTION 4 - FIRST AID MEASURES

**Description of First Aid Measures First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical attention (show the label where possible).

**First-aid Measures After Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Seek medical attention.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Flush with copious quantities of water for 15 minutes. Seek medical advice.

**First-aid Measures After Eye Contact:** Immediately flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting.

**Most important symptoms and effects, both acute and delayed Symptoms/Injuries:** Not expected to present a significant hazard under anticipated conditions of normal use. May cause an allergic reaction in sensitive individuals. Please refer to the package insert for more detailed information.

### Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical attention (show the label where possible).

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## SECTION 5 - FIRE FIGHTING MEASURES

### Extinguishing Media

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

### Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid all unnecessary exposure. Do not breathe vapor or mist.

### For Non-emergency Personnel

**Protective Equipment:** Use appropriate personal protection equipment (PPE). Refer to section 8.2.

**Emergency Procedures:** Evacuate unnecessary personnel.

### For Emergency Responders

**Protective Equipment:** Equip clean-up 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.

**Reference to Other Sections:** See heading 8, Exposure Controls and Personal Protection.

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## SECTION 7 - HANDLING AND STORAGE

### 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 original container. Store in a dry, cool and well-ventilated place.

**Incompatible Products:** Strong bases. Strong oxidizers.

**Storage Temperature:** 20 - 25 °C (68 - 77 °F) Excursions permitted to 15 - 30 °C (59 - 86 °F) (See USP Controlled Room Temperature).

**Specific End Use(s):** Pharmaceutical.

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control Parameters:** For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

### Sodium chloride

Latvia OEL - TWA : 5 mg/m<sup>3</sup>

Lithuania OEL - TWA : 5 mg/m<sup>3</sup>

### Hydrochloric Acid:

USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

### Exposure Controls

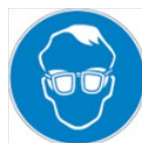
**Appropriate Engineering Controls:** Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

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**Personal Protective Equipment:** Gloves. Safety glasses.



- Hand Protection** : Wear chemically resistant protective gloves.  
**Eye Protection** : Chemical goggles or safety glasses.  
**Skin and Body Protection** : Wear suitable protective clothing. Wash contaminated clothing before reuse.  
**Respiratory Protection** : In case of inadequate ventilation wear respiratory protection.  
**Other Information** : When using, do not eat, drink or smoke.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### Information on Basic Physical and Chemical Properties

- Physical State** : Liquid  
**Appearance** : Clear, colorless  
**Odor** : Benzyl Alcohol  
**Odor Threshold** : No data available  
**pH** : 2.0 - 3.0  
**Evaporation Rate** : No data available  
**Melting Point** : No data available  
**Freezing Point** : No data available  
**Boiling Point** :  $\approx 100\text{ }^{\circ}\text{C}$  (212  $^{\circ}\text{F}$ )  
**Flash Point** : No data available  
**Auto-ignition Temperature** : No data available  
**Decomposition Temperature** : No data available  
**Flammability (solid, gas)** : Not applicable  
**Vapor Pressure** : No data available  
**Relative Vapor Density at 20  $^{\circ}\text{C}$**  : No data available  
**Relative Density** : No data available  
**Specific Gravity** :  $\approx 1.0$   
**Solubility** : Soluble in water  
**Partition Coefficient: N-Octanol/Water** : No data available  
**Viscosity** : No data available

### Other Information

No additional information available

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## SECTION 10 - STABILITY AND REACTIVITY

**Reactivity:** Hazardous reactions will not occur under normal conditions

**Chemical Stability:** Stable under recommended handling and storage conditions (see sec. 7).

**Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.

**Conditions to Avoid:** Direct sunlight. Extremely high or low temperatures

**Incompatible Materials:** Strong oxidizers. Strong bases

**Hazardous Decomposition Products:** Thermal decomposition generates: Carbon oxides (CO, CO<sub>2</sub>), Halogenated compounds, Nitrogen oxides

## SECTION 11 - TOXICOLOGY INFORMATION

### Information On Toxicological Effects

**Acute Toxicity:** Not classified

**Water (7732-18-5):**

**LD50 Oral Rat** : >90000 mg/kg

**Glycopyrronium bromide (Glycopyrrolate):  
(596-51-0)**

**LD50 Oral Rat** : 709 mg/kg

**Hydrogen chloride (7647-01-0):**

**LD50 Oral Rat** : 238 - 277 mg/kg

**LD50 Dermal Rat** : > 5010 mg/kg

**LC50 Inhalation Rat** : 1.68 mg/l (Exposure time: 1 h)

**LC50 Inhalation Rat** : 781 ppm/4h (reported as 3124 ppm/1 h)

**Skin Corrosion/Irritation** : Not classified (**pH**: 2 - 3)

**Serious Eye Damage/Irritation** : Not classified (**pH**: 2 - 3)

**Respiratory or Skin Sensitization** : Not classified

**Germ Cell Mutagenicity** : Not classified

**Carcinogenicity** : Not classified

**Hydrochloric acid (7647-01-0)**

**IARC group** : 3

**Reproductive Toxicity** : Not classified

**Specific Target Organ Toxicity (Single Exposure)** : Not classified

**Specific Target Organ Toxicity**

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(Repeated Exposure) : Not classified  
Aspiration Hazard : Not classified

## Sodium Chloride:

Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

## Irritation/ Sensitization:

Eye irritation	Rabbit	Moderate
Skin irritation	Rabbit	Mild

## SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

**Persistence and Degradability** : Not established  
**Glycopyrrolate Injection, USP**  
**Bioaccumulative Potential** : Not established  
**Mobility in Soil** : No additional information available  
**Other Adverse Effects**  
**Other Information** : Avoid release to the environment.

## SECTION 13 - DISPOSAL INFORMATION

### Waste treatment methods

**Sewage Disposal Recommendations:** Do not empty into drains; dispose of this material and its container in a safe way.

**Waste Disposal Recommendations:** Dispose of waste material in accordance with all local, regional, national, and international regulations.

## SECTION 14 - TRANSPORTATION INFORMATION

**In Accordance with DOT** : Not regulated for transport  
**In Accordance with IMDG** : Not regulated for transport  
**In Accordance with IATA** : Not regulated for transport

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## SECTION 15 - REGULATORY INFORMATION

### US Federal Regulations:

<b>Water (7732-18-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Hydrochloric acid (7647-01-0)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
Listed on United States SARA Section 313	
<b>SARA Section 302 Threshold Planning Quantity (TPQ)</b>	500 (gas only)
<b>SARA Section 313 - Emission Reporting:</b>	1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

### US State Regulations:

<b>Hydrochloric acid (7647-01-0)</b>
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
U.S. - Pennsylvania - RTK (Right to Know) List

### Sodium Chloride:

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

## SECTION 16 - OTHER DATA

**Other Information:** This document has been prepared in accordance with the Information from published literature.

### GHS Full Text Phrases:

Acute Tox. 3 (Inhalation: gas)	:	Acute toxicity (inhalation: gas) Category 3
Acute Tox. 3 (Inhalation: vapour)	:	Acute toxicity (inhalation: vapor) Category 3
Acute Tox. 4 (Dermal)	:	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Oral)	:	Acute toxicity (oral) Category 4
Aquatic Acute 2	:	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	:	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Dam. 1	:	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	:	Serious eye damage/eye irritation Category 2A
Eye Irrit. 2B	:	Serious eye damage/eye irritation Category 2B



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Flam. Liq. 4	:	Flammable liquids Category 4
Met. Corr. 1	:	Corrosive to metals Category 1
Skin Corr. 1A	:	Skin corrosion/irritation Category 1A
Skin Irrit. 2	:	Skin corrosion/irritation Category 2
STOT SE 3	:	Specific target organ toxicity (single exposure) Category 3
H227	:	Combustible liquid
H290	:	May be corrosive to metals
H302	:	Harmful if swallowed
H312	:	Harmful in contact with skin
H314	:	Causes severe skin burns and eye damage
H315	:	Causes skin irritation
H318	:	Causes serious eye damage
H319	:	Causes serious eye irritation
H320	:	Causes eye irritation
H331	:	Toxic if inhaled
H335	:	May cause respiratory irritation
H401	:	Toxic to aquatic life
H402	:	Harmful to aquatic life

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