

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Gly-AUS/DP-004

Effective Date: 03 October 2025

GLYCOPYRRONIUM BROMIDE (GLYCOPYRROLATE) INJECTION 0.2 MG/1 ML

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Glycopyrrolate Accord Injection 0.2 mg/1 mL

Sponsor

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

Telephone: 1800 222 673
(hours 8:30am – 4:30pm)

SECTION 2 – HAZARD(S) IDENTIFICATION

Classification of the Substance or Mixture:

GHS – Classification:

Acute Toxicity, Oral	: Category 4
Skin Irritation	: Category 2
Eye Irritation	: Category 2A
Specific Target Organ Toxicity	: Single Exposure 3

Label Elements:



Signal Word: Warning

Hazard Statements:

H302	- Harmful if swallowed
H315	- Causes skin irritation
H319	- Causes serious eye irritation

Precautionary Statements:

P264	- Wash hands thoroughly after handling.
P271	- Use in a well-ventilated area.
P280	- Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P312	- If swallowed: Call a Poison Center or doctor/physician if you feel unwell.

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- P302 + P352 - If on skin: wash with plenty of water.
P305 + P351 + P338 - If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P330 - Rinse mouth.
P332 + P313 - If skin irritation occurs: Get medical advice/attention.
P337 + P313 - If eye irritation persists: Get medical advice/attention.
P362 - Take off contaminated clothing and wash it before reuse.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, state, federal and provincial regulations.

Other Hazards: Exposure may aggravate individuals with pre-existing skin, kidney, liver, and pulmonary disorders.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Active: Glycopyrronium bromide (Glycopyrrolate)

Inactive: Sodium chloride, Hydrochloric acid, Water for Injection

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Glycopyrronium bromide (Glycopyrrolate)	596-51-0	209-887-0	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2B, H320 STOT SE 3, H335	0.02
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Hydrochloric acid	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	Used to adjust pH
Water for Injection	7732-18-5	231-791-2	Not Listed	99.1

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

SECTION 4 - FIRST AID MEASURES

Description of Necessary First Aid Measures:

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Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known.

Medical Attention and Special Treatment: If you are unwell, see medical attention.

SECTION 5 - FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture: Hazardous reactions will not occur under normal conditions.

Special Protective Equipment and Precautions for Fire-Fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and 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.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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SECTION 7 - HANDLING AND STORAGE

Precautions for Safe Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product.

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.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters – Exposure Standards, Biological Monitoring:

Hydrochloric acid:

ACGIH Ceiling Threshold Limit	: 2 ppm
NIOSH REL	: 7 mg/m ³
	5 ppm
IDLH	: 50 ppm
OSHA PEL	: 7 mg/m ³
	5 ppm

Sodium chloride:

Latvia OEL - TWA	: 5 mg/m ³
Lithuania OEL - TWA	: 5 mg/m ³

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: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare provider (i.e., an end user such as a clinician/ doctor/ nurse) for its sole intended parental (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to airborne concentrations and environmental conditions. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g use a NIOSH- or CEN-certified respirator.. Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Solution
Colour	:	Clear, colourless
Odour	:	No data available
Odour Threshold	:	No data available
Solvent Solubility	:	No data available
Water Solubility	:	No data available
pH	:	2.0-3.0
Melting/Freezing Point (°C)	:	No data available
Boiling Point and boiling range (°C)	:	No data available
Partition Coefficient (<i>Water for Injection</i>)	:	No data available
Sodium Chloride	:	No data available
Hydrochloric acid	:	No data available
Decomposition Temperature (°C)	:	No data available
Evaporation Rate (Gram/s)	:	No data available
Vapour Pressure (kPa)	:	No data available
Vapour Density (g/ml)	:	No data available
Relative Density	:	No data available
Osmolarity	:	270-320 mOsmol/kg H ₂ O
Auto-ignition Temperature (Solid) (°C)	:	No data available

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Flammability (Solids)	:	No data available
Flash Point (Liquid) (°C)	:	No data available
Upper Flammability or Explosive Limits (Liquid) (% by Vol.)	:	No data available
Lower Flammability or Explosive Limits (Liquid) (% by Vol.)	:	No data available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials and Possible Hazardous Reactions: As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition Products: No data available.

SECTION 11 – TOXICOLOGICAL INFORMATION

The information included in this section describes the potential hazards of the active ingredient.

Information on Toxicological Effects:

Short Term: Harmful if inhaled, or eye or skin contact, or swallowed Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Skin contact may result in inflammation characterized by itching, scaling, reddening, blistering, pain or dryness. Eye contact may result in redness, pain or severe eye damage. Inhalation may cause irritation of the lungs and respiratory system. Overexposure may result in serious illness or death.

Long Term: No data available.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include fast, slow or irregular heart beats, flushing, unable to sweat, feeling sick or vomiting, dry mouth, dry and/or itchy skin, constipation, difficulty urinating, impotence, reduced milk supply in breastfeeding women, blurred vision or other problems with your eyesight, headache, nervousness, drowsiness, dizziness, fever, or nausea.

Acute Toxicity:

Glycopyrronium bromide (Glycopyrrolate):

Species	Route	End Point	Dose
Rat	Oral	LD 50	709 mg/kg

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Sodium Chloride:

Species	Route	End Point	Dose
Rat	Oral	LD 50	3000 mg/kg
Mouse	Oral	LD 50	4000 mg/kg

Water:

Species	Route	End Point	Dose
Rat	Oral	LD 50	>9 0000 mg/kg

Irritation / Sensitization:

Study Type	Species	Severity
Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

Carcinogen Status: Not listed as a carcinogen by NTP or OSHA.

SECTION 12 – ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity: No data available.

Persistence and Degradability: No data available.

Bio-accumulative Potential: No data available.

Mobility in Soil: No data available.

Other Adverse Effects: No data available.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

SECTION 14 - TRANSPORTATION INFORMATION

The following refers to all modes of transportation unless specified below.

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Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15 - REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Glycopyrronium bromide (Glycopyrrolate):

CERCLA/SARA 313 Emission reporting	: Not Listed
California Proposition 65	: Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons	: Schedule 4
EU EINECS/ELINCS List	: 209-887-0

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

Hydrochloric acid:

CERCLA/SARA 313 Emission reporting	: 1.0%
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	: 5000lb 2270 kg
California Proposition 65	: Not Listed
Inventory - United States TSCA - Sect. 8(b)	: Present
Australia (AICS)	: Present
Standard for the Uniform Scheduling for Drugs and Poisons:	: Schedule 5 Schedule 6
EU EINECS/ELINCS List	: 231-595-7

Water for Injection:

CERCLA/SARA 313 Emission reporting	: Not Listed
California Proposition 65	: Not Listed
Inventory - United States TSCA - Sect. 8(b)	: Present
Australia (AICS)	: Present
REACH - Annex IV - Exemptions from the obligations of Register	: Present
EU EINECS/ELINCS List	: 231-791-2

SECTION 16 - OTHER INFORMATION

Abbreviations:

ACGIH	: American Conference of Governmental Industrial Hygienists
AICS	: Australian Inventory of Chemical Substances
AIHA	: American Industrial Hygiene Association
ANSI	: American National Standards Institute

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CAS	: Number Chemical Abstract Service Registry Number
CERCLA	: Comprehensive Environmental Response Compensation and Liability Act
CHAN	: Chemical Hazard Alert Notice
CHEMTREC	: Chemical Transportation Emergency Center
DOT	: Department of Transportation
DSL	: Domestic Substances List
ECHA	: European Chemicals Agency
EINECS	: European Inventory of Existing Commercial Chemical Substances
ELINCS	: European List of Notified Chemical Substances
EPA	: Environmental Protection Agency
GHS	: Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	: High Efficiency Particulate Air (Filter)
HMIS	: Hazardous Materials Identification System
IARC	: International Agency for Research on Cancer
ICAO/IATA	: International Civil Aviation Organization/International Air Transport
IMO	: International Maritime Organization
KOW	: Octanol/Water Partition Coefficient
LEL	: Lower Explosive Limit
MSDS	: Material Safety Data Sheet
MSHA	: Mine Safety and Health Administration
NA	: Not Applicable, except in Section 14 where NA = North America
NE	: Not Established
NADA	: New Animal Drug Application
NAIF	: No Applicable Information Found
NCI	: National Cancer Institute
NDSL	: Non-Domestic Substances List
NFPA	: National Fire Protection Association
NIOSH	: National Institute for Occupational Safety and Health
NPDES	: National Pollutant Discharge Elimination System
NOS	: Not Otherwise Specified
NTP	: National Toxicology Program
OSHA	: Occupational Safety and Health Administration
OEL	: Occupational Exposure Limit
PEL	: Permissible Exposure Limit (OSHA)
RCRA	: Resource Conservation and Recovery Act
RQ	: Reportable Quantity
RTECS	: Registry of Toxic Effects of Chemical Substances
SARA	: Superfund Amendments and Reauthorization Act
SDS	: Safety Data Sheet
STEL	: Short Term Exposure Limit
TLV	: Threshold Limit Value (ACGIH)
TPQ	: Threshold Planning Quantity
TSCA	: Toxic Substances Control Act
TWA	: Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	: Upper Explosive Limit
UN	: United Nations
USP	: United States Pharmacopeia
WEEL	: Workplace Environmental Exposure Level (AIHA)

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WHMIS : Workplace Hazardous Materials Information System

Data Sources: Information from published literature.

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