

SAFETY DATA SHEET

Section 1: Identification	
Material	Glycopyrrolate Oral Solution 1mg/5mL
Recommended use	Pharmaceutical product
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard statements	Harmful if swallowed.
Precautionary statements	Use personal protective equipment as required. Wash thoroughly after handling If swallowed: Call a Poison center or doctor/physician if you feel unwell. IF exposed or concerned: Get medical advice/attention. Store locked up. Dispose of contents/container in accordance with local/regional/national/international regulations
Additional information: Restricted to professional users. Other hazards Results of PBT and vPvB assessment PBT: Not applicable. vPvB: Not applicable.	
Section 3: Composition/Information on Ingredients	
Ingredients	Glycopyrrolate
CAS	596-51-0
Section 4: First-Aid Measures	
After swallowing	Rinse mouth. Do not induce vomiting. Call for a doctor immediately.
Inhalation	Supply fresh air; consult doctor in case of complaints
Skin Contact	Immediately wash with water and soap and rinse thoroughly.
Eye Contact	Rinse opened eye for several minutes under running water.
Information for doctor:	No further relevant information available
Most important symptoms and	

effects, both acute and delayed	
Indication of any immediate medical attention and special treatment needed	No further relevant information available.
General information: Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.	
Section 5: Fire-Fighting Measures	
Special hazards arising from the substance or mixture	Formation of toxic gases is possible during heating or in case of fire.
Extinguishing Media Suitable extinguishing agents:	CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Advice for firefighters Protective equipment	Wear self-contained respiratory protective device.
Section 6: Accidental Release Measures	
Protective Precautions, Protective Equipment and Emergency Procedures:	Wear protective clothing.
Environmental Precautions:	Do not allow to enter sewers/ surface or ground water.
Methods and Material For Containment and Cleaning Up:	Dispose of contaminated material as waste
Section 7: Handling and Storage	
Handling: Precautions for safe handling	Store in cool, dry place in tightly closed receptacles. Open and handle receptacle with care.
Information about fire and explosion protection	Keep respiratory protective device available
Storage: Requirements to be met by storerooms and receptacles: Store in a cool location. Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle. Keep container in a well-ventilated place. Keep away from sources of ignition and heat.	
Specific end use(s) No further relevant information available.	
Section 8: Exposure Controls/Personal Protection	
Personal protection equipment:	
General protective and hygienic measures	Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Store protective clothing separately.
Respiratory protection	Not required.

Protection of hands	The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
Material of gloves	The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
Penetration time of glove material	The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
Eye protection	Safety glasses
Section 9: Physical and Chemical Properties	
Physical Form	Solution
Colour	Clear
Description	Glycopyrrolate Oral Solution 1 mg/5 mL is a clear, cherry-flavored solution. 16 oz (473 mL) bottle NDC 71785-1021-0
Section 10: Stability and Reactivity	
Chemical stability	Stable under normal conditions
Reactivity	Stable under normal conditions.
Thermal decomposition / conditions to be avoided	Formation of toxic gases is possible during heating or in case of fire
Possibility of hazardous reactions	No dangerous reactions known
Conditions to avoid	Heat
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Formation of toxic gases is possible during heating or in case of fire
Section 11: Toxicological Information	
Information On Toxicological Effects	
Acute Toxicity:	Not classified
Glycopyrronium bromide (Glycopyrrolate) (596-51-0)	
LD50 Oral Rat	709 mg/kg
Section 12: Ecological Information	
Toxicity	No further relevant information available.
Aquatic toxicity	
Persistence and degradability	No further relevant information available
Behaviour in environmental systems: Bioaccumulative potential	No further relevant information available

Mobility in soil	No further relevant information available
Additional ecological information	General notes: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water. Do not allow undiluted product to reach ground water, water course or sewage system.
Results of PBT and vPvB assessment PBT: Not applicable. vPvB: Not applicable. Other adverse effects No further relevant information available.	
Section 13: Disposal Considerations	
Waste treatment methods · Recommendation	Must not be disposed of together with household garbage. Do not allow product to reach sewage system
Uncleaned packaging Recommendation	Dispose of in accordance with national regulations
Section 14: Transport Information	
UN-Number ADR, ADN, IMDG, IATA	Not applicable
Transport hazard class(es) ADR, ADN, IMDG, IATA	Not applicable
Packing group ADR, IMDG, IATA	Not applicable
Environmental hazards: Marine pollutant:	Not applicable
Special precautions for user	Not applicable
Section 15: Regulatory Information	
Safety, health and environmental regulations/legislation specific for the substance or mixture Philippines Inventory of Chemicals and Chemical Substances - Substance is not listed. Australian Inventory of Chemical Substances - Substance is listed. Standard for the Uniform Scheduling of Drugs and Poisons- Substance is not listed. Chemical safety assessment: A Chemical Safety Assessment has not been carried out.	
Section 16: Other Information	
Issue Date : 14-06-2022 Version : 00 Further information Revision date: New issue Revision note: New issue <p>The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.</p> <p>Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.</p>	