

SAFETY DATA SHEET

Section 1: Identification	
Material	Dicyclomine Hydrochloride Tablets USP, 20 mg
Recommended use	Pharmaceutical product
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sanga Reddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
<p>Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer -specific information about this product when used according to the physicians directions, Pharmaceutical Agent -handling of this product in its final form presents minimal occupational exposure risk</p> <p>This product is a drug, as defined by the US food, Drug, and cosmetic Act (21 U.S.C.301et seq.) and by Canada's Food and Drugs Act. It is in solid, final form for direct administration to the patient. Therefore, is it exempt from the US2012 Hazard communication standard, as defined in the 29 CFR 1910.1200(b)(5) (iii) and in Canada's Hazardous Products Act.</p>	
Section 3: Composition/Information on Ingredients	
Name	CAS
Colloidal Silicon Dioxide	7631-86-9
Corn Starch	9005-25-8
FD & C Blue	NA
Lactose Monohydrate	10039-26-6
Hypromellose	9004-65-3
Sodium Starch Glycolate	9063-38-1
Stearic Acid	57-11-4
Section 4: First-Aid Measures	
Description of First Aid Measures	
General	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.
Inhalation	The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist

Skin Contact	Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.
Eye Contact	The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
Ingestion	Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention (show the label where possible)
Most Important Symptoms and Effects both Acute and Delayed	
General	Please refer to the package insert for more detailed
Inhalation	None expected under normal conditions of use.
Skin Contact	May cause mild skin irritation.
Eye Contact	May cause minor eye irritation.
Ingestion	Pharmaceutical. Ingestion is likely to be harmful or have adverse effects.
Chronic symptoms	Not available
Section 5: Fire-Fighting Measures	
Extinguishing Media	
Suitable extinguishing media	Not flammable. Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	None Known.
Special Hazards Arising from the substance or mixture	
Fire hazard	Not flammable
Explosion hazard	Product is not explosive.
Reactivity	Hazardous reactions will not occur under normal conditions
Advice for Firefighters	
Precautionary measures	Exercise caution when fighting any chemical fire
Firefighting instructions	Use water spray or fog for cooling exposed containers.
Protection during firefighting	Do not enter fire area without proper protective equipment, including respiratory protection.
Hazardous Combustion Products	Carbon oxides (CO, CO ₂).
Other information	Refer to section 9 for flammability properties.
Section 6: Accidental Release Measures	
Personal Precautions, Protective Equipment and Emergency Procedures	
General measures	Avoid all contact with skin, eyes, or clothing. Avoid generating dust.
For Non-Emergency Personnel	
Protective equipment	Use appropriate personnel protection equipment (PPE)
Emergency procedures	Evacuate unnecessary personnel.

For Emergency Personnel	
Protective equipment	Use appropriate personnel protection equipment (PPE)
Emergency procedures	Evacuate unnecessary personnel. Avoid creating/spreading dust. Prevent entry to sewers/public waters
Environmental Personnel	
Methods and Material for Containment and Cleaning Up	
Methods for cleaning up	For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal. Avoid generating dust.
Reference to other sections	See heading 8, Exposure controls and personal protection.
Section 7: Handling and Storage	
Precautions for Safe Handling	
Patients/ consumers	Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.
Hygiene measures	This SDS is for a pharmaceutical agent-Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapour or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after
Conditions for Safe Storage, including any Incompatibilities	
Storage conditions	Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.
Specific End Use(s)	Pharmaceutical. Refer to product insert for usage instructions and product information
8. Exposure controls / personal protection	
Control Parameters	Not applicable
Exposure Controls	
Appropriate Engineering Controls	Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommend exposure limits.
Personal protective equipment	Not generally required. The use of personal protective equipment may be necessary as conditions warrant.
Hand protection	Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR

Eye protection	In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended						
Skin and body protection	In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible						
Respiratory protection	When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if found to be necessary.						
Section 9: Physical and Chemical Properties							
Physical State	Tablet						
Description	<p>20 mg light blue to blue, round, unscored, flat faced beveled edge tablets debossed with 'V1' on one side and '44' on other side.</p> <table> <tr> <td>Bottles of 100s</td><td>NDC 31722-079-01</td></tr> <tr> <td>Bottles of 500s</td><td>NDC 31722-079-05</td></tr> <tr> <td>Bottles of 1000s</td><td>NDC 31722-079-10</td></tr> </table> <p>Store at 20° to 25°C (68°F to 77°F). [See USP Controlled Room Temperature.]</p>	Bottles of 100s	NDC 31722-079-01	Bottles of 500s	NDC 31722-079-05	Bottles of 1000s	NDC 31722-079-10
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Section 10: Stability and Reactivity	
Reactivity	Hazardous reactions will not occur under normal conditions.
Chemical Stability	Stable under normal conditions.
Possibility of Hazardous Reactions	Hazardous polymerization will not occur.
Conditions to Avoid	Direct sunlight. Extremely high or low temperatures. Avoid creating or spreading dust.
Incompatible Materials	Strong oxidizers, Strong bases, strong acids.
Hazardous Decomposition Products	Carbon oxides (CO, CO ₂)
Section 11: Toxicological Information	
Information on Toxicological Effects - Product	
Acute toxicity	Not classified
LD50 and LC50 Data	Not available
Skin Corrosion/Irritation	Not classified
Serious Eye damage/Irritation	Not classified
Respiratory or skin sensitization	Not classified
Germ cell Mutagenicity	Not classified
Teratogenicity	Not available
Carcinogenicity	Not classified
Specific target organ toxicity (Repeated exposure)	Not classified
Reproductive Toxicity (Single Exposure)	Not classified
Aspiration Hazard	Not classified
Information on Toxicological Effects-Ingredients(s) LD50 and LC50 Data: Not available	
Section 12: Ecological Information	
Toxicity: Not available Persistence and Degradability: Not available Bio accumulative Potential: Not available	
Section 13: Disposal Considerations	
Waste disposal recommendations: Do not dispose of waste into sewer .Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.	
Section 14: Transport Information	
In accordance with ICAO/IATA/DOT/TDG UN number Not regulated for transport UN proper shipping name : Nor regulated for transport	

Section 15: Regulatory Information

US Federal Regulations: Not applicable

US state Regulations: Not applicable

This product has been classified in accordance with the hazard criteria of the controlled products Regulations (CPR) and the SDS contains all of the information required by CPR.

Section 16: Other Information, including date of preparation or last revision

Issue Date: 13-11-2024

Version: 00

Further information

Revision date: NA

Revision note: NA

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.

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.