

**SAFETY DATA SHEET**

<b>Section 1: Identification</b>	
<b>Material</b>	Dicyclomine Hydrochloride Capsules USP, 10 mg
<b>Recommended use</b>	Pharmaceutical product
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sanga Reddy, Telangana 502313, India (IND)
<b>Distributor</b>	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
<b>Section 2: Hazard(s) Identification</b>	
<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>	
<b>Section 3: Composition/Information on Ingredients</b>	
<b>Name</b>	<b>CAS</b>
Calcium sulfate dihydrate	10101-41-4
Gelatin	9000-70-8
FD & C Blue	NA
FD & C Red	NA
Lactose Monohydrate	10039-26-6
Magnesium stearate	557-04-0
Pregelatinized starch	9005-25-8
Sodium lauryl sulfate	151-21-3
Povidone	9003-39-8
Propylene glycol	57-55-6
Shellac	9000-59-3
Sodium hydroxide	1310-73-2
Titanium dioxide	13463-67-7

<b>Section 4: First-Aid Measures</b>	
<b>Description of First Aid Measures</b>	
<b>General</b>	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.
<b>Inhalation</b>	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
<b>Skin Contact</b>	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.
<b>Eye Contact</b>	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.
<b>Ingestion</b>	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)
<b>Most Important Symptoms and Effects both Acute and Delayed</b>	
<b>General</b>	Please refer to the package insert for more detailed
<b>Inhalation</b>	None expected under normal conditions of use.
<b>Skin Contact</b>	May cause mild skin irritation.
<b>Eye Contact</b>	May cause minor eye irritation.
<b>Ingestion</b>	Pharmaceutical. Ingestion is likely to be harmful or have adverse effects.
<b>Chronic symptoms</b>	Not available
<b>Section 5: Fire-Fighting Measures</b>	
<b>Extinguishing Media</b>	
<b>Suitable extinguishing media</b>	Not flammable. Use extinguishing media appropriate for surrounding fire.
<b>Unsuitable extinguishing media</b>	None Known.
<b>Special Hazards Arising from the substance or mixture</b>	
<b>Fire hazard</b>	Not flammable
<b>Explosion hazard</b>	Product is not explosive.
<b>Reactivity</b>	Hazardous reactions will not occur under normal conditions
<b>Advice for Firefighters</b>	
<b>Precautionary measures</b>	Exercise caution when fighting any chemical fire
<b>Firefighting instructions</b>	Use water spray or fog for cooling exposed containers.
<b>Protection during firefighting</b>	Do not enter fire area without proper protective equipment, including respiratory protection.
<b>Hazardous Combustion Products</b>	Carbon oxides (CO, CO <sub>2</sub> ).
<b>Other information</b>	Refer to section 9 for flammability properties.

<b>Section 6: Accidental Release Measures</b>	
<b>Personal Precautions, Protective Equipment and Emergency Procedures</b>	
<b>General measures</b>	Avoid all contact with skin, eyes, or clothing. Avoid generating dust.
<b>For Non-Emergency Personnel</b>	
<b>Protective equipment</b>	Use appropriate personnel protection equipment (PPE)
<b>Emergency procedures</b>	Evacuate unnecessary personnel.
<b>For Emergency Personnel</b>	
<b>Protective equipment</b>	Use appropriate personnel protection equipment (PPE)
<b>Emergency procedures</b>	Evacuate unnecessary personnel. Avoid creating/spreading dust. Prevent entry to sewers/public waters
<b>Environmental Personnel</b>	
<b>Methods and Material for Containment and Cleaning Up</b>	
<b>Methods for cleaning up</b>	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.
<b>Reference to other sections</b>	See heading 8, Exposure controls and personal protection.
<b>Section 7: Handling and Storage</b>	
<b>Precautions for Safe Handling</b>	
<b>Patients/ consumers</b>	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.
<b>Hygiene measures</b>	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 handling.
<b>Conditions for Safe Storage, including any Incompatibilities</b>	
<b>Storage conditions</b>	Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.
<b>Specific End Use(s)</b>	Pharmaceutical. Refer to product insert for usage instructions and product information

8. Exposure controls / personal protection	
<b>Control Parameters</b>	Not applicable
<b>Exposure Controls</b>	
<b>Appropriate Engineering Controls</b>	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.
<b>Personal protective equipment</b>	Not generally required. The use of personal protective equipment may be necessary as conditions warrant.
<b>Protective equipment</b>	
<b>Hand protection</b>	Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR
<b>Eye protection</b>	In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended
<b>Skin and body protection</b>	In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible
<b>Respiratory protection</b>	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	
<b>Physical State</b>	Capsule
<b>Description</b>	<p>10 mg capsules, light blue to blue colour transparent hard gelatin cap/light blue to blue colour transparent hard gelatin body, size '4' capsules imprinted with 'V1' in white on cap and '41' in white on body filled with white to off white granular powder.</p> <p>Bottles of 100s <span style="float: right;">NDC 31722-052-01</span></p> <p>Bottles of 500s <span style="float: right;">NDC 31722-052-05</span></p> <p>Bottles of 1000s <span style="float: right;">NDC 31722-052-10</span></p> <p>Store at 20° to 25°C (68°F to 77°F). [See USP controlled room temperature.]</p>

<b>Section 10: Stability and Reactivity</b>	
<b>Reactivity</b>	Hazardous reactions will not occur under normal conditions.
<b>Chemical Stability</b>	Stable under normal conditions.
<b>Possibility of Hazardous Reactions</b>	Hazardous polymerization will not occur.
<b>Conditions to Avoid</b>	Direct sunlight. Extremely high or low temperatures. Avoid creating or spreading dust.
<b>Incompatible Materials</b>	Strong oxidizers, Strong bases, strong acids.
<b>Hazardous Decomposition Products</b>	Carbon oxides (CO, CO <sub>2</sub> )
<b>Section 11: Toxicological Information</b>	
<b>Information on Toxicological Effects - Product</b>	
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	
<b>Section 12: Ecological Information</b>	
Toxicity: Not available Persistence and Degradability: Not available Bio accumulative Potential: Not available	
<b>Section 13: Disposal Considerations</b>	
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.	
<b>Section 14: Transport Information</b>	
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.