

**SAFETY DATA SHEET**

<b>Section 1: Identification</b>	
<b>Material</b>	Sapropterin Dihydrochloride Tablets 100 mg
<b>Recommended use</b>	Laboratory chemicals
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
<b>Distributor</b>	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
<b>Section 2: Hazard(s) Identification</b>	
<b>Classification of the substance or mixture</b>	This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)
<b>Hazard Statements</b>	Harmful if swallowed
<b>Prevention</b>	Wash face, hands and any exposed skin thoroughly after handling
<b>Ingestion</b>	If swallowed: Call a Poison Center or doctor/physician if you feel unwell Rinse mouth
<b>Section 3: Composition/Information on Ingredients</b>	
<b>Active Ingredient</b>	Sapropterin Dihydrochloride
<b>CAS</b>	69056-38-8
<b>Section 4: First-Aid Measures</b>	
<b>Eye Contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention
<b>Skin Contact</b>	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.
<b>Inhalation</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
<b>Ingestion</b>	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.
<b>Most important symptoms and effects</b>	None reasonably foreseeable.
<b>Notes to Physician</b>	Treat symptomatically
<b>Section 5: Fire-Fighting Measures</b>	
<b>Suitable extinguishing media</b>	Water spray, carbon dioxide (CO <sub>2</sub> ), dry chemical, alcohol-resistant foam.

<b>Specific Hazards Arising from the Chemical</b>	Keep product and empty container away from heat and sources of ignition
<b>Hazardous Combustion Products</b>	Carbon monoxide (CO). Carbon dioxide (CO <sub>2</sub> ). Nitrogen oxides (NO <sub>x</sub> ). Hydrogen chloride
<b>Protective Equipment and Precautions for Firefighters</b>	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
<b>Section 6: Accidental Release Measures</b>	
<b>Personal Precautions</b>	Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.
<b>Environmental Precautions</b>	Should not be released into the environment
<b>Methods for Containment and Clean Up</b>	Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.
<b>Section 7: Handling and Storage</b>	
<b>Handling</b>	Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation
<b>Storage</b>	Keep container tightly closed. To maintain product quality: Store in freezer. Incompatible Materials. Strong oxidizing agents.
<b>8. Exposure controls / personal protection</b>	
<b>Exposure Guidelines</b>	This product does not contain any hazardous materials with occupational exposure limits established by the region
<b>Engineering Measures</b>	Ensure adequate ventilation, especially in confined areas.
<b>Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection
<b>Skin and body protection</b>	Wear appropriate protective gloves and clothing to prevent skin exposure
<b>Respiratory Protection</b>	Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a
<b>Hygiene Measures</b>	Handle in accordance with good industrial hygiene and safety practice

Section 9: Physical and Chemical Properties	
<b>Physical State</b>	Solid Tablet
<b>Description</b>	100 mg sapropterin dihydrochloride, are off-white to light yellow mottled round, tablets debossed with "I 1" on one side and plain on other side.  Bottle of 120 tablets NDC 31722-045-12
Section 10: Stability and Reactivity	
<b>Reactive Hazard</b>	None known, based on information available
<b>Stability</b>	Stable under recommended storage conditions
<b>Conditions to Avoid</b>	Incompatible products
<b>Incompatible Materials</b>	Strong oxidizing agents
<b>Hazardous Decomposition Products</b>	Carbon monoxide (CO), Carbon dioxide (CO <sub>2</sub> ), Nitrogen oxides (NO <sub>x</sub> ), Hydrogen chloride
<b>Hazardous Polymerization</b>	Hazardous polymerization does not occur
<b>Hazardous Reactions</b>	None under normal processing
Section 11: Toxicological Information	
<b>Other Adverse Effects</b>	The toxicological properties have not been fully investigated
<b>Acute Toxicity</b>	
<b>LD50 Oral</b>	Sapropterin dihydrochloride 1g/kg (Rat)
Section 12: Ecological Information	
<b>Ecotoxicity</b>	Do not empty into drains
<b>Persistence and Degradability</b>	Soluble in water Persistence is unlikely based on information available
<b>Bioaccumulation/ Accumulation</b>	No information available.
<b>Mobility</b>	Will likely be mobile in the environment due to its
Section 13: Disposal Considerations	
<b>Waste treatment methods</b>	Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification
Section 14: Transport Information	
<b>DOT</b>	Not regulated
<b>TDG</b>	Not regulated
<b>IATA</b>	Not regulated
<b>IMDG/IMO</b>	Not regulated

### Section 15: Regulatory Information

#### U.S. Federal Regulations

**SARA 313** Not applicable

**SARA 311/312 Hazard Categories** See section 2 for more information

**CWA (Clean Water Act)** Not applicable

**Clean Air Act** Not applicable

**OSHA - Occupational Safety and Health Administration**

Not applicable

**CERCLA** Not applicable

**California Proposition 65** This product does not contain any Proposition 65 chemicals.

#### U.S. State Right-to-Know

##### Regulations

Not applicable

#### U.S. Department of Transportation

Reportable Quantity (RQ): N

DOT Marine Pollutant N

DOT Severe Marine Pollutant N

#### U.S. Department of Homeland

##### Security

This product does not contain any DHS chemicals.

#### Other International Regulations

**Mexico - Grade** No information available

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

**Issue Date:** 17-11-2022

**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.