

SAFETY DATA SHEET

Section 1: Identification	
Material	Sapropterin dihydrochloride Powder for Oral Solution 100 mg/packet and 500 mg/packet
Recommended use	Laboratory chemicals
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	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Not classified
Classification according to Directive 67/548/EEC or 1999/45/EC	Not classified
Adverse physicochemical, human health and environmental effects	No additional information available
Prevention	Wash face, hands and any exposed skin thoroughly after handling. Do not eat, drink or smoke when using this product
Ingestion	If swallowed: Call a Poison Center or doctor/physician if you feel unwell Rinse mouth
Section 3: Composition/Information on Ingredients	
Active Ingredient	CAS
Sapropterin Dihydrochloride	69056-38-8
Ascorbic acid	50-81-7
Mannitol	69-65-8
Potassium Citrate Monohydrate Granular	6100-05-6
Sucralose	56038-13-2
Section 4: First-Aid Measures	
Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.

Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
Ingestion	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.
Most important symptoms and effects	None reasonably foreseeable.
Notes to Physician	Treat symptomatically
Section 5: Fire-Fighting Measures	
Suitable extinguishing media	Water spray, carbon dioxide (CO ₂), dry chemical, alcohol-resistant foam.
Specific Hazards Arising from the Chemical	Keep product and empty container away from heat and sources of ignition
Hazardous Combustion Products	Carbon monoxide (CO). Carbon dioxide (CO ₂). Nitrogen oxides (NO _x). Hydrogen chloride
Protective Equipment and Precautions for Firefighters	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
Section 6: Accidental Release Measures	
Personal Precautions	Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.
Environmental Precautions	Should not be released into the environment
Methods for Containment and Clean Up	Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.
Section 7: Handling and Storage	
Handling	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
Storage	Keep container tightly closed. To maintain product quality: Store in freezer. Incompatible Materials. Strong oxidizing agents.
8. Exposure controls / personal protection	
Exposure Guidelines	This product does not contain any hazardous materials with occupational exposure limits established by the region.
Engineering Measures	Ensure adequate ventilation, especially in confined areas.
Personal Protective Equipment	
Eye/face Protection	Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection
Skin and body protection	Wear appropriate protective gloves and clothing to prevent skin exposure

Respiratory Protection	Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a
Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice

Section 9: Physical and Chemical Properties													
Physical State	Powder												
Description	<p>Sapropterin Dihydrochloride Powder for Oral Solution Supplied as off-white to yellow powder supplied in unit dose packets as follows: 100 mg sapropterin dihydrochloride per packet:</p> <table border="0"> <tr> <td>Carton of 30 unit dose packets</td> <td>NDC 31722-047-30</td> </tr> <tr> <td>Single unit dose packet</td> <td>NDC 31722-047-01</td> </tr> <tr> <td>Carton of 1 unit dose packet</td> <td>NDC 31722-047-31</td> </tr> </table> <p>500 mg sapropterin dihydrochloride per packet:</p> <table border="0"> <tr> <td>Carton of 30 unit dose packets</td> <td>NDC 31722-048-30</td> </tr> <tr> <td>Single unit dose packet</td> <td>NDC 31722-048-01</td> </tr> <tr> <td>Carton of 1 unit dose packet</td> <td>NDC 31722-048-31</td> </tr> </table>	Carton of 30 unit dose packets	NDC 31722-047-30	Single unit dose packet	NDC 31722-047-01	Carton of 1 unit dose packet	NDC 31722-047-31	Carton of 30 unit dose packets	NDC 31722-048-30	Single unit dose packet	NDC 31722-048-01	Carton of 1 unit dose packet	NDC 31722-048-31
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Section 10: Stability and Reactivity													
Reactive Hazard	None known, based on information available												
Stability	Stable under recommended storage conditions												
Conditions to Avoid	Incompatible products												
Incompatible Materials	Strong oxidizing agents												
Hazardous Decomposition Products	Carbon monoxide (CO), Carbon dioxide (CO ₂), Nitrogen oxides (NO _x), Hydrogen chloride												
Hazardous Polymerization	Hazardous polymerization does not occur												
Hazardous Reactions	None under normal processing												
Section 11: Toxicological Information													
Other Adverse Effects	The toxicological properties have not been fully investigated												
Acute Toxicity													
LD50 Oral	Sapropterin dihydrochloride 1g/kg (Rat)												
Section 12: Ecological Information													
Ecotoxicity	Do not empty into drains												
Persistence and Degradability	Soluble in water Persistence is unlikely based on information available												
Bioaccumulation/ Accumulation	No information available.												

Mobility	Will likely be mobile in the environment due to its water solubility
Section 13: Disposal Considerations	
Waste treatment methods	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	
DOT	Not regulated
TDG	Not regulated
IATA	Not regulated
IMDG/IMO	Not regulated
Section 15: Regulatory Information	
<p>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.</p> <p>U.S. State Right-to-Know Regulations Not applicable</p> <p>U.S. Department of Transportation Reportable Quantity (RQ): N DOT Marine Pollutant N DOT Severe Marine Pollutant N</p> <p>U.S. Department of Homeland Security This product does not contain any DHS chemicals.</p> <p>Other International Regulations Mexico - Grade No information available</p>	

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

Issue Date: 10-11-2023

Version: 02

Further information

Revision date: 10-11-2023

Revision note:

01. Excipient details included in section 3.

02. Updated Section 2.

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.