

SAFETY DATA SHEET

Section 1: Identification	
Material	Aminocaproic Acid Oral Solution USP, 0.25 g/ mL
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	
Inhalation	Harmful if inhaled. May cause irritation to respiratory tract
Ingestion	Harmful if ingested
Skin Contact	May be harmful by skin absorption. May cause irritation
Eye Contact	May cause irritation
Physical Hazards	None known
Chronic Exposure	Hypersensitivity; cardiac and hepatic lesions; myopathy, myalgia and necrosis of muscle fibers.
Conditions Aggravated by Exposure	Hypotension; acute renal failure; clotting or thrombosis in the renal pelvis and ureters; active intravascular clotting.
Systemic Effects	Fibrinolysis-inhibitory effects. Repeated, excessive ingestion may cause CNS and laxative effects.
Section 3: Composition/Information on Ingredients	
Active Ingredient	Aminocaproic Acid
CAS	60-32-2
Section 4: First-Aid Measures	
General	In case of accident involving illness, seek medical advice immediately.
Eye Contact	Remove contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Obtain medical attention.
Skin Contact	Remove contaminated clothing. Flush skin with plenty of water. Obtain medical attention.
Ingestion	Seek medical advice immediately.
Inhalation	Remove to fresh air. Seek medical advice immediately. If not breathing, trained personnel should give artificial respiration. If difficulty in breathing, trained personnel should give oxygen.

Section 5: Fire-Fighting Measures	
Extinguishing media	Use extinguishing media appropriate to the surrounding fire
Special considerations	Toxic gases and vapors may be released if involved in a fire
Section 6: Accidental Release Measures	
Small spill	Utilize appropriate personal protective equipment. Gather spilled material and place in a glass or plastic container. Assess and document the amount of material collected.
Large spill	Contain spill to the extent possible using available absorbents. Prevent entry into water systems, surface waters, or groundwater. Notify the appropriate emergency response personnel. Do not attempt clean-up without appropriate protective equipment
Section 7: Handling and Storage	
Store at 20°C to 25°C (68°F to 77°F) [See USP controlled room temperature]. This product is best stored in the original container	
Section 8: Exposure controls / personal protection	
Exposure Limits	Not established.
Personal Protection Recommendations	
Ventilation	A local and/or general exhaust system is recommended to minimize airborne contaminants
Respirator	Use a powered or air-purifying respirator meeting an approved standard if indicated by environmental assessment. Selection should be based upon anticipated exposure and capacity of respirator
Gloves	Impervious gloves should be worn
Clothing	Wear clean, body-covering protective clothing that is suitable for the task being performed
Eye Protection	Utilize safety eyewear that complies with an approved standard when protection from splash, mist or dust is required.

Section 9: Physical and Chemical Properties	
Physical State	Liquid
Description	Aminocaproic Acid Oral Solution, USP, 0.25 g/mL Each mL of raspberry-flavored oral solution contains 0.25 g/mL of aminocaproic acid, USP. 8 Fl. Oz. (236.5 mL) Bottle NDC 31722-035-23
Section 10: Stability and Reactivity	
Stability	Stable under normal conditions of use
Hazardous Decomposition Products	Toxic gases and vapors may be released if involved in a fire
Incompatibilities	Not established.
Section 11: Toxicological Information	
Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.	
Toxicity data	Aminocaproic Acid: Oral LD50 (mouse)=14300 mg/kg Intravenous LD50 (rat)=3300 mg/kg Subcutaneous LD50 (mouse)=5790 mg/kg Intravenous LD50 (dog)=2150 mg/kg
Carcinogenicity:	No adequate studies in animals have been performed to determine the carcinogenic potential of this product
Reproductive Effects:	Pregnancy Category C. No adequate or well-controlled studies have been conducted with this product.
Section 12: Ecological Information	
Not established. This product is a mixture that has not been tested as a whole	
Section 13: Disposal Considerations	
Ensure compliance with local, state and federal regulations	
Section 14: Transport Information	
Refer to the bill of lading for proper shipping information. Special considerations: N/A	
Section 15: Regulatory Information	
Individual containers are labeled in accordance with U.S. FDA regulations for finished pharmaceutical products. Drug Status: Rx Only Schedule: Non-controlled Product may be considered a hazardous material according to OSHA 29 CFR 1910.1200 regulatory standards.	

Section 16: Other Information, including date of preparation or last revision**Issue Date: 10-01-2023****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.