SAFETY DATA SHEET

Aminocaproic Acid Tablets USP, 500 mg and 1000 mg
Version: 01 **Issue Date: 02/14/2024**

1. IDENTIFICATION:

Product Name: Aminocaproic Acid Tablets USP, 500 mg and 1000 mg

Recommended Use: Rx. Pharmaceutical. Use only as directed.

Uses Advised Against: Pharmaceutical product used in enhancing homeostasis when fibrinolysis contributes to bleeding

Distributor: **Biocon Pharma Inc.,**
485, US Highway 1 S, Ste B-305,
Iselin, New Jersey, 08830-3009
USA
Emergency: (732) 636-2950 or call 911
Information: (732) 636-2950

Manufacturer: Carnegie Pharmaceuticals LLC
600, Delran pkwy, Unit C,
Delran, New Jersey, 08075
USA
Emergency: (732) 783-7011 or call 911
Information: (732) 783-7011

2. HAZARDS IDENTIFICATION:

Classification of the substance or mixture
GHS Classification: Not Classified as Hazardous

Label Elements:

Signal Word: Not Classified
Hazard Statements: Not Classified in accordance with international standards for workplace safety

Other Hazards: No data available.

3. COMPOSITION / INFORMATION ON INGREDIENT:

Ingredient	CAS number	GHS Classification
Aminocaproic Acid, USP	60-32-2	Not Listed
Povidone, USP	9003-39-8	Not Listed
Crospovidone, NF	9003-39-8	Not Listed
Steatic Acid, NF	57-11-4	Not Listed
Magnesium Stearate, NF	557-04-0	Not Listed

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

4. FIRST AID MEASURES:

This is a pharmaceutical product in its final form. The following guidance may be used as needed.
Eye Contact: Flush with water immediately for 15 minutes and seek medical attention.
Skin Contact: In event of occupational contact, remove the contaminated clothing and rinse with excess water in the exposed area.
Ingestion: In the case of accidental ingestion, seek medical advice
Inhalation: Move individual to fresh air. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES:

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.
Special Hazards Arising from the Substance or Mixture: Formation of toxic gases is possible during heating or fire.
Advice for Fire-Fighters: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES:

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods and Material for Containment and Cleaning Up
Contain the source of spill if it is safe to do so. If applicable, collect spill with absorbent material. Clean spill area thoroughly.

7. HANDLING AND STORAGE:

Precautions for safe handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for safe storage, including any incompatibilities.
Handle and store per label and other instructions to maintain product integrity.

Specific end use(s)
Pharmaceutical Product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Aminocaproic Acid
Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m3 to 3000ug/m3).
Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent).

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical state: Solid.
Form: Tablet.
Color: White to off-white.
Odor: Not available.
Odor threshold: Not available.
pH: Not available.
Melting point/freezing point: Not available.
Initial boiling point and boiling range: Not available.
Flash point: Not available.
Evaporation rate: Not available.
Flammability (solid, gas): Not available.
Upper/lower flammability or explosive limits
Flammability limit – lower (%): Not available.
Flammability limit – upper (%): Not available.
Explosive limit - lower (%): Not available.
Explosive limit - upper (%): Not available.
Vapor pressure: Not available.
Vapor density: Not available.
Relative density: Not available.
Solubility
Solubility (water): Not available.
Partition coefficient (n-octanol/water): Not available.
Auto-ignition temperature: Not available.
Decomposition temperature: Not available.
Viscosity: Not available.
Other information
Explosive properties: Not explosive.
Oxidizing properties: Not oxidizing.

10. STABILITY AND REACTIVITY:

Stable under recommended storage conditions. Incompatible with strong oxidizing agents.

11 TOXICOLOGICAL INFORMATION:

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: Not acutely toxic (based on animal data). Accidental ingestion may cause effects similar to those seen in clinical use. See package insert for additional information.

Known Clinical Effects: Effects reported during clinical use include headache, dizziness, nausea, diarrhea, gastrointestinal disturbances, decrease in blood pressure (hypotension), ringing of the ears, nasal congestion, skin rash, changes in blood chemistry.

Acute Toxicity: (Species, Route, End Point, Dose)

Aminocaproic Acid
Rat Oral LD50 > 10,000 mg/kg
Mouse Oral LD50 12,000 mg/kg
Dog Oral LD50 > 7000 mg/kg
Rat Intravenous LD50 3200 mg/kg
Mouse Intravenous LD50 3000 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)
Aminocaproic Acid
Eye Irritation Mild Moderate

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))
Aminocaproic Acid
Reproductive & Fertility Rat Oral ~500 mg/kg/day LOAEL Fertility

Carcinogen Status
None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Additional Information
No data available.

12 ECOLOGICAL INFORMATION:

No information available

13 DISPOSAL CONSIDERATIONS:

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. National, State, and local specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14 TRANSPORT INFORMATION:
Refer to the bill of lading for proper shipping information.
Special considerations: N/A

15 REGULATORY INFORMATION:

This product is an FDA regulated pharmaceutical product that may not be classified, regulated and/or is exempt from certain requirements contained in 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Consult product packaging insert for additional health and safety information on dosage and potential side effects from use of this product.
Drug Status: Rx Only

16 OTHER INFORMATION:
Not applicable

****

The information herein is provided in good faith and is believed to be accurate as of the effective date shown. However, no warranty, express or implied, is given. Carnegie Pharmaceutical, LLC makes no representation as to the comprehensiveness or accuracy of the information. Conditions of use are beyond Carnegie Pharmaceutical, LLC's control and therefore users are responsible to verify this data under their own operating conditions to determine whether the product is suitable for their particular purposes, and they assume all risks of their use, handling, and disposal of the product. Carnegie Pharmaceutical, LLC expressly disclaims any and all liability as to any results obtained, or arising from, any use of this publication or reliance upon information contained herein.

****