

SAFETY DATA SHEET

Aminocaproic Acid Oral Solution, USP

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Revised: 01/14/20
Supersedes: N/A

I. IDENTIFICATION:

Recommended Use: Rx Pharmaceutical for human use

Chemical Name: Aminocaproic Acid Oral Solution USP

Distributor: VistaPharm, Inc.
7265 Ulmerton Rd
Largo, FL 33771, USA
Emergency: (727) 530-1633
Information: (727) 530-1633

Manufacturer: Sovereign Pharmaceuticals, LLC
7590 Sand Street
Fort Worth, TX 76118

II. HAZARDS IDENTIFICATION:

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 hazardous ingredients. See section XI, *Toxicological Information* for additional data.



Toxic;
Irritant (e.g., skin,
eye, respiratory)

Signal Word:
WARNING

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|------------------------------------|--|
| 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. |

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III. COMPOSITION / INFORMATION ON INGREDIENTS:

Contains:

| <u>Active Ingredient:</u> | <u>CAS Number:</u> | <u>Strength:</u> |
|---------------------------|--------------------|------------------|
| Aminocaproic Acid | 60-32-2 | 1.25 g per 5 mL |

| <u>Inactive Ingredient:</u> | <u>CAS Number:</u> | <u>Inactive Ingredient:</u> | <u>CAS Number:</u> |
|-----------------------------|--------------------|-----------------------------|--------------------|
| Citric Acid | 77-92-9 | Propylparaben | 94-13-3 |
| Edetate Disodium | 6381-92-6 | Sorbitol Solution | 50-70-4 |
| Methylparaben | 99-76-3 | Raspberry Flavor | N/A |
| Purified Water | 7732-18-5 | Saccharin Sodium | 128-44-9 |

IV. 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.

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.

Ingestion: Seek medical advice immediately. Provide container labeling or SDS if possible.

V. 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.

VI. 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.

VII. 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.

VIII. 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.

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IX. PHYSICAL AND CHEMICAL PROPERTIES:

Product Strength: Aminocaproic Acid USP: 1.25 g per 5 mL
Physical State: liquid
Color: colorless to slightly yellow
Shape: N/A
Deboss/Imprint: N/A
Aroma: Raspberry
Specific Gravity: 1.06 – 1.16
pH: 6.0 – 6.5
Boiling point: Unknown (20% of this mixture has a boiling point of 221°F)

Flashpoint, Viscosity, Vapor pressure, Odor threshold, Vapor density, Upper/lower flammability or explosive limits, Relative density, Melting point/Freezing point, Solubility, Partition coefficient: n-octanol/water, Auto-ignition temperature, Evaporation rate, and Decomposition temperature: No information available

X. 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. This product is a mixture that has not been tested as a whole.

XI. 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.

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| 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. |

XII. ECOLOGICAL INFORMATION:

Not established. This product is a mixture that has not been tested as a whole.

XIII. DISPOSAL CONSIDERATIONS:

Ensure compliance with local, state and federal regulations.

XIV. TRANSPORT INFORMATION:

Refer to the bill of lading for proper shipping information.

Special considerations: N/A

XV. 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.

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XVI. OTHER INFORMATION:

| | | | | |
|--------------------------------|-----------------|-----------------------|---------------------|--------------|
| NFPA (self-assessment): | Health=1 | Flammability=1 | Reactivity=0 | |
| HMIS (self-assessment): | Health=1 | Flammability=1 | Reactivity=0 | PPE=F |

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