

SAFETY DATA SHEET

Aminocaproic Acid Oral Solution USP, 0.25 g/mL

Version: 01

Issue Date: 02/14/2024

1. IDENTIFICATION:

Product Name: Aminocaproic Acid Oral Solution USP, 0.25 g/mL

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 in accordance with 29 CFR 1910 (OSHA HCS)

Skin corrosion/irritation: Category 2 (H315)

Serious eye damage/ eye irritation: Category 2 (H319)

STOT-SE: Category 3 (respiratory system) (H335)

Signal Word: **Warning**

P202: Do not handle until all safety precautions are read and understood.

P264: Wash hands thoroughly after handling product

P302+P352: If ON SKIN: wash with plenty of soap and water

P332+P313: If skin irritation or rash occurs: Get medical attention or advice.

P305+P351+P358: If IN EYES: Rinse continuously with water for several minutes. Remove contacts if present and easy to do. Get medical attention or advice.

P304+P341: If INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a comfortable position for breathing.

P273: Avoid release to the environment.

Hazards not otherwise classified (HNOC) or not covered by GHS - None

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3. COMPOSITION / INFORMATION ON INGREDIENT:

Ingredient	CAS number	GHS Classification
Aminocaproic Acid, USP	60-32-2	Skin corrosion/irritation Cat 2 Serious eye damage/eye irritation Cat 2 STOT-SE Cat 3 (respiratory system)
Methylparaben, NF	99-76-3	Serious eye damage/eye irritation Cat 2
Propylparaben, NF	94-13-3	Serious eye damage/eye irritation Cat 2
Edetate Disodium, USP	6381-92-6	Acute toxicity-oral Cat 4 Serious eye damage/eye irritation Cat 2 STOT-SE Cat 3 (respiratory system) (aqueous, not anhydrous, form in powder)
Sodium Saccharin, USP	128-44-9	Not Listed
Citric Acid Anhydrous, USP	77-92-9	Serious eye damage/eye irritation Cat 2 (aqueous, not anhydrous, form in powder)
Neosorb 70/20B, USP	50-70-4	Not Listed
Raspberry Flavor, NAT WONF	N/A Mixture	Not Listed
Very Raspberry Flavor, Artificial	N/A Mixture	Not Listed
Masking Agent Flavor, Artificial	N/A Mixture	Not Listed
Purified Water, USP	7732-18-5	Not Listed

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: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special Hazards Arising from the Substance or Mixture: Carbon oxides.

Advice for Fire-Fighters: Wear self-contained breathing apparatus for fire fighting if necessary.

6. ACCIDENTAL RELEASE MEASURES:

Personal Precautions, Protective Equipment and Emergency Procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. For personal protection see section 8.

Environmental Precautions

Do not allow the product to enter drains.

Methods and Material for Containment and Cleaning Up

Pick up and arrange disposal without creating dust. Mop up. Keep in suitable, closed containers for disposal.

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7. HANDLING AND STORAGE:

Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.

Conditions for safe storage, including any incompatibilities.

Store locked up.

Keep container tightly closed in a dry and well-ventilated place. Recommended storage temperature: room temperature or refrigerated.

Specific end use(s)

Aminocaproic Acid Oral Solution, 0.25 g/ml is a pharmaceutical preparation used to treat bleeding caused by problems with the blood clotting system.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION:

None

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Follow approved Good Manufacturing Practices. Local exhaust ventilation is normally not required.

Personal protective equipment

Eye/face protection

Safety glasses with side-shields.

Skin protection

Handle with gloves to prevent skin contact and product contamination. Product components may be absorbed through the skin.

Body Protection

Wear appropriate covering to prevent dusting and contamination of work clothing.

Respiratory protection

Use approved respirators and components when mixing, formulating or packaging products.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Product Strength: 0.25 g/mL

Physical State: Oral Solution

Appearance: Colorless to pale yellow liquid, free from particulate matter, Raspberry-flavored

pH: No data available.

Melting pint/freezing point: No data available.

Flash point: No data available.

Oxidizing Properties: No data available.

10. STABILITY AND REACTIVITY:

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

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11 TOXICOLOGICAL INFORMATION:

Acute toxicity

No data available for the formulated product.

Aminocaproic Acid (100%)

LD50 14500 mg/kg Oral, mouse

Skin corrosion/irritation

No data available for the formulated product.

Serious eye damage/eye irritation

May be irritating to eyes

Respiratory or skin sensitization

May cause skin or respiratory irritation

Germ cell mutagenicity

Product not classified

Carcinogenicity

No data available for the formulated product.

Reproductive toxicity

No data available for formulated product.

Specific target organ toxicity - single exposure

No data available for formulated product. Respiratory irritation is possible.

Specific target organ toxicity - repeated exposure

No data available for formulated product.

Aspiration hazard

No data available for the formulated product.

Additional Information

No data available.

12 ECOLOGICAL INFORMATION:

No information available

13 DISPOSAL CONSIDERATIONS:

Waste treatment methods.

Dispose in accordance with local, state, and federal regulations. Do not dispose of waste in sanitary waste sewer. Ensure product waste disposal follows FDA guidelines.

Contaminated packaging

Dispose of unused products.

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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

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