

# SAFETY DATA SHEET

Amicar<sup>®</sup> Oral Solution

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Revised: 5/13/15  
Supersedes: 3/19/13

MF #: 909B

## I. IDENTIFICATION:

**Recommended Use:** Rx Pharmaceutical for human use

**Chemical Name:** Aminocaproic Acid Oral Solution USP

**MF#:** 909B

**Distributor:** Clover Pharmaceuticals  
1775 West Oak Parkway, Suite 800  
Marietta, GA 30062  
Emergency: (770) 499-8100  
Information: (770) 499-8100

**Manufacturer:** Mikart, Incorporated  
1750 Chattahoochee Ave., N.W.  
Atlanta, GA 30318  
Emergency: (404) 351-4510  
Information: (404) 351-4510

## 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**

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	N&A Raspberry Flavor	N/A
Purified Water	7732-18-5	Saccharin Sodium	128-44-9
Artificial Bitterness	N/A		

## 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.

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:**

<b>NFPA (self-assessment):</b>	<b>Health=1</b>	<b>Flammability=1</b>	<b>Reactivity=0</b>	
<b>HMIS (self-assessment):</b>	<b>Health=1</b>	<b>Flammability=1</b>	<b>Reactivity=0</b>	<b>PPE=F</b>

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