

SECTION 1: IDENTIFICATION
1.1. Product Identifier

Product Form: Mixture

Product Name: Aminocaproic Acid Injection, USP

Product Code: 0517-9120-25; 0517-9191-25

1.2. Intended Use of the Product

Use of the Substance/Mixture: Aminocaproic Acid Injection is useful in enhancing hemostasis when fibrinolysis contributes to bleeding. In life-threatening situations, fresh whole blood transfusions fibrinogen infusions, and other emergency measures may be required.

1.3. Name, Address, and Telephone of the Responsible Party
Company

American Regent, Inc.

5 Ramsey Road

P.O. Box 9001

Shirley, NY

1-800-645-1706

www.americanregent.com

1.4. Emergency Telephone Number

Emergency Number : CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION
2.1. Classification of the Substance or Mixture
GHS-US Classification

Not classified

2.2. Label Elements
GHS-US Labeling

No labeling applicable

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions. Personnel with hemopoietic and renal disorders may have increased sensitivity to this product.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Water	(CAS-No.) 7732-18-5	74.1	Not classified
Hexanoic acid, 6-amino-	(CAS-No.) 60-32-2	25	Comb. Dust
Benzyl alcohol	(CAS-No.) 100-51-6	0.9	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation: dust, mist), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401
Sodium hydroxide	(CAS-No.) 1310-73-2	*	Met. Corr. 1, H290 Acute Tox. 3 (Oral), H301 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

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Hydrochloric acid	(CAS-No.) 7647-01-0	*	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
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Full text of H-phrases: see section 16

* Sodium hydroxide and Hydrochloric acid are added to adjust pH when necessary.

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation. May cause an allergic reaction in sensitive individuals.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation. May cause an allergic reaction in sensitive individuals.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may be harmful or have adverse effects.

Chronic Symptoms: None known.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive. Contains substances that are combustible dusts. If dried and allowed to accumulate, may form combustible dust concentrations in air that could ignite and cause an explosion. Take appropriate precautions.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers. Do not breathe fumes from fires or vapors from decomposition.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Thermal decomposition generates: Carbon oxides (CO, CO₂). Nitrogen oxides. Sodium oxides. Chlorine oxides. Irritating or toxic vapors.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

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Emergency Procedures: Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mist, spray. Do not mix with other drugs. This product contains benzyl alcohol as a preservative. Contains substances that are combustible dusts. If dried and allowed to accumulate, may form combustible dust concentrations in air that could ignite and cause an explosion. Take appropriate precautions.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, and spray. Use appropriate personal protective equipment (PPE).

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool and well-ventilated place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Protect from sunlight.

Storage Temperature: Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) (See USP Controlled Room Temperature).

Incompatible Materials: Strong acids, strong bases, strong oxidizers. Water reactive materials. Light. Humidity.

7.3. Specific End Use(s)

Aminocaproic Acid Injection is useful in enhancing hemostasis when fibrinolysis contributes to bleeding. In life-threatening situations, fresh whole blood transfusions fibrinogen infusions, and other emergency measures may be required.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Benzyl alcohol (100-51-6)		
USA AIHA	WEEL TWA (ppm)	10 ppm
Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
USA IDLH	US IDLH (mg/m ³)	10 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³
Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	7 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

8.2. Exposure Controls

Appropriate Engineering Controls

: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

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Personal Protective Equipment : Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing : Chemically resistant materials and fabrics.
Hand Protection : Wear protective gloves.
Eye and Face Protection : Chemical safety goggles.
Skin and Body Protection : Wear suitable protective clothing.
Respiratory Protection : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
Environmental Exposure Controls : Avoid release to the environment.
Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid
Appearance : Clear, colorless
Odor : Benzyl alcohol
Odor Threshold : No data available
pH : 6.0 - 7.6
Evaporation Rate : No data available
Melting Point : No data available
Freezing Point : No data available
Boiling Point : ≈ 214 °F (≈ 101.11 °C)
Flash Point : No data available
Auto-ignition Temperature : No data available
Decomposition Temperature : No data available
Flammability (solid, gas) : Not applicable
Vapor Pressure : No data available
Relative Vapor Density at 20°C : No data available
Relative Density : No data available
Solubility : No data available
Partition Coefficient: N-Octanol/Water : No data available
Viscosity : No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).
10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
10.4. Conditions to Avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials. Humidity.
10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers. Water reactive materials. Light. Humidity.
10.6. Hazardous Decomposition Products: None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

Hexanoic acid, 6-amino- (60-32-2)	
LD50 Oral Rat	> 10 g/kg
Benzyl alcohol (100-51-6)	
LD50 Oral Rat	1230 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 4.178 mg/l/4h

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ATE (Dust/Mist)	1.50 mg/l/4h
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	140 - 340 mg/kg
Hydrochloric acid (7647-01-0)	
LD50 Dermal Rabbit	> 5010 mg/kg

Skin Corrosion/Irritation: Not classified

pH: 6.0 - 7.6

Serious Eye Damage/Irritation: Not classified

pH: 6.0 - 7.6

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation. May cause an allergic reaction in sensitive individuals.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation. May cause an allergic reaction in sensitive individuals.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may be harmful or have adverse effects.

Chronic Symptoms: None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Benzyl alcohol (100-51-6)	
LC50 Fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	23 mg/l (Exposure time: 48 h - Species: water flea)
LC50 Fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
ErC50 (Algae)	770 mg/l
Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l
Hydrochloric acid (7647-01-0)	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)

12.2. Persistence and Degradability

Aminocaproic Acid Injection, USP	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Aminocaproic Acid Injection, USP	
Bioaccumulative Potential	Not established.
Benzyl alcohol (100-51-6)	
Log Pow	1.1

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

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Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Hexanoic acid, 6-amino- (60-32-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Benzyl alcohol (100-51-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

15.2. US State Regulations

Benzyl alcohol (100-51-6)	
U.S. - Massachusetts - Right To Know List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Sodium hydroxide (1310-73-2)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Hydrochloric acid (7647-01-0)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 08/07/2019
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Inhalation: dust, mist)	Acute toxicity (inhalation: dust, mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Comb. Dust	Combustible Dust

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Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 4	Flammable liquids Category 4
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H227	Combustible liquid
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H401	Toxic to aquatic life
H402	Harmful to aquatic life

Refer to American Regent prescribing information for further information at: <http://www.americanregent.com/AllProducts.aspx>

The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall American Regent, Inc., its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if American Regent, Inc. has been advised of the possibility of such damages.

SDS US (GHS HazCom)