



SAFETY DATA SHEET

Tranexamic Acid Injection, USP

Section 1. Chemical Product and Company Information	
Product	Tranexamic Acid Injection, USP
Chemical Name(s):	trans-4-(aminomethyl)cyclohexanecarboxylic acid
Product Form	Sterile Solution for Intravenous Injection
Product NDC#	61990-0611-2
Synonym	Tranexamic Acid Injection
CAS Number	1197-18-8
RTECS #	GU8400000
Trade Name	CYKLOKAPRON
Chemical Formula	<i>C₈H₁₅NO₂</i>
Contact Information	Apollo Pharmaceuticals USA Inc. 4400 PGA Blvd. Suite 102, Palm Beach Gardens, FL 33410, USA Tel.: (561) 469-9058, Fax: (561) 727 8943
Emergency Phone Number	National Poison Control 1-800-222-1222
<div style="display: flex; justify-content: space-around; align-items: center;">   </div>	
Section 2: Hazards Identification	
<p>Hazard pictograms (GHS-US):</p> <div style="text-align: center; margin: 10px 0;">  </div> <p>Potential Acute Health Effects: Hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation</p> <p>Potential Chronic Health Effects: Not available.</p> <p>Carcinogenic Effects: Not available.</p> <p>Mutagenic Effects: Not available</p> <p>Teratogenic Effects: Not available</p> <p>Developmental Toxicity: Repeated or prolonged exposure is not known to aggravate medical conditions.</p> <p>Adverse effects: Not available</p>	



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Section 3: Composition and Information on Ingredients

Composition:

<u>Name</u>	<u>CAS #</u>	<u>% by Weight</u>
Tranexamic Acid	1197-18-8	10
Water for Injection	7732-18-5	90

Section 4. First Aid Measures

General: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention.

Inhalation: If difficulty breathing, administer oxygen. If necessary, provide artificial respiration. Seek medical attention immediately.

Skin contact: In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Seek medical attention immediately. Serious skin contact: Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention immediately.

Eye contact: Check for and remove any contacts lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Seek medical attention immediately.

Ingestion: Ingestion may cause adverse effects.

Notes to physician: See product package insert for complete information.

Overdose Treatment: Not available.

Section 5. Fire-fighting Measures

Flammability of the product: May be combustible at high temperatures.

Combustion Products: These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂...).

Unusual Fire and Explosion Hazards: Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks. Risks of explosion of the product in presence of mechanical impact: not available. Risks of explosion of the product in presence of static discharge: not available. Fine particles may fuel fires/explosions.



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Extinguishing Media and instruction:

Small fire: Use DRY chemical powder. **Large fire:** Use water spray, fog or foam. Do NOT use water jet.

Protective equipment & precautions for firefighters: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

Special remarks on fire hazard: Not available

Special remarks on explosion hazard: Not available

Section 6. Accidental Release Measures

Release to land:

Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local, state, and federal regulations.

Large Spill: Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum. Finish cleaning by spreading water on the contaminated surface and clean surface thoroughly to remove residual contamination. Collect in suitable container for disposal. For proper waste disposal, see section 13 of the SDS.

Release to air: Not available

Release to Water: Refer to local water authority; drain disposal is not recommended.

Protective equipment: Keep unnecessary personnel away. Wear approved respiratory protection, chemical safety goggles, chemically compatible gloves and protective clothing such as protective coveralls and shoe covers for spills.

Section 7. Handling and Storage

Handling: As a general rule, when handling Tranexamic Acid Solution for Injection, avoid all contact and inhalation of mists, and/or vapors associated with this material.

Keep locked up. Keep away from heat, sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. DO NOT ingest. Avoid contact with skin. Wear suitable protective clothing in case of insufficient ventilation. If you feel unwell, seek medical attention and show label when possible. Use only in accordance with directions.

Storage: Keep container tightly closed. Keep container in a cool, well ventilated area. Store at 25°C (77°F); excursions permitted to 15°–30°C (59°–86°F) [see USP Controlled Room Temperature]. Refer to label instructions to ensure product quality and integrity.

Incompatibilities: Keep away from strong oxidizing agents



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Section 8. Exposure Control / Personal Protection

Engineering Controls: No special ventilation requirements. May use process enclosure, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generates fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Splash goggles. Lab coat. Nitrile or latex gloves. Respirator. Be sure to use an approved/certified respirator or equivalent. In case of large spill:

In case of Large Spill: Splash goggles. Full suit. Respirator. Boots. Nitrile or latex gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Respiratory Protection: Under normal use, respirators are not required. If vapor or mists are generated, use a disposable mask (N95). Personnel wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.

Exposure limit: Not available

Section 9. Physical and chemical properties

Physical appearance: Liquid
Color: Colorless
Molecular Weight: 157.21 g/mole
Taste: Not available
Odor: Mild
Odor Threshold: Not available
pH: 6.5 – 8.0
Melting Point: Not available
Freezing Point: Not available
Boiling Point: ≈ 100°C (212°F)
Flash Point: Not available
Evaporation rate: Not available

Flammability: Not available
Upper Flammable Limit: Not available
Lower Flammable Limit: Not available
Vapor Pressure: Not available
Vapor Density: Not available
Relative Density: Not available
Partition Coefficient: Not available
Auto-Ignition Temperature: Not available
Decomposition Temperature: Not available
Viscosity: Not available
Dispersion Properties: Not Established
Solubility: Easily soluble in cold water

Section 10. Stability and reactivity

Reactivity: Reactive with oxidizing agents.
Chemical stability: The product is stable.
Possibility of hazardous reaction: Not Available
Conditions to avoid: Excess heat and oxidizing agents.
Incompatible materials: Reactive with oxidizing agents.
Hazardous decomposition products: Nitrogen oxides.



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Corrosivity: Non-corrosive in presence of glass.

Polymerization: Will not occur.

Section 11. Toxicological information

Routes of exposure: Inhalation and ingestion.

Symptoms:

Short term: Hazardous in case of skin contact (irritant), of ingestion (with nausea vomiting and diarrhea), of inhalation (irritant).

Long term: Prolonged or repeated ingestion may affect metabolism. The toxicological properties of this substance have not been fully investigated.

Reproductive toxicity: May cause adverse reproductive effects based on animal data. No human data found. Excreted in maternal milk in human. Passes through the placental barrier in human.

FDA Pregnancy Category: B

Toxicity to animals:

Oral Rat: LD50: >10,000 mg/kg

Oral Mouse: LD50: >10,000 mg/kg

Measures of toxicity: Not available

Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) and/or Registry of Toxic Effects of Chemical Substance (RTECS).

Section 12. Ecological information

Ecotoxicity: Not available

Bioaccumulation potential: Not available

Products of biodegradation: Possibly hazardous short-term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the products of biodegradation: The product itself and its products of degradation are not toxic.

Section 13. Disposal Information

Waste classification: Not available

Waste from residues/unused products: Dispose of waste in accordance with all applicable federal, state and local laws.



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Waste Disposal: Waste must be disposed of in accordance with federal, state and local environment control regulations.

Section 14. Transport Information

DOT Classification: Not a DOT controlled material (United States).

UN Number: Not available

UN Shipping name: Not available

Transport hazard class: Not available

Packing Group: Not available

Environmental hazard: Not available

Transport in bulk: Not available

Special precautions needed with transport: Not available

Section 15 Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: no products found.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC): R36/37/38-Irritating to eyes, respiratory system and skin. S2- keep out of the reach of children. S24/25- avoid contact with skin and eyes. S46- if swallowed, seek medical advice immediately and show the container or label.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 0

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 1

Flammability: 0

Reactivity: 0

US OSHA Classification: Gloves, lab coat, Respirator. Be sure to use an approved/certified respirator or equivalent and splash goggles.

Section 16. Additional Information

References: Not available

Created: September 16, 2019



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Last Updated: Not applicable

Prepared & Approved by: Apollo Pharmaceuticals USA Inc.

The above information is believed to be accurate and represents the best information currently available to Apollo Pharmaceuticals USA Inc. The use of this product should be through or under the direction of a licenced physician or a registered healthcare practitioner. This SDS does not address therapeutic use of this product. Apollo Pharmaceuticals USA Inc. makes no warranties, express 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. In no event should Apollo Pharmaceuticals USA Inc. be liable for any claim, loss, or damage of any third party, even if Apollo Pharmaceuticals USA Inc. has been advised of the possibility of such damages to occur.