

SAFETY DATA SHEET

1. **Identification**

Product Identifier: Tranexamic Acid Injection 1000 mg/10 mL

Synonyms: trans -4-(Aminomethyl)cyclohexanecarboxylic acid

National Drug Code (NDC): 17478-217-10

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. **Hazard(s) Identification**

Physical Hazards: Not classified as hazardous.

Health Hazards: Not classified as hazardous.

Symbol(s): None.

Signal Word: None.

Hazard Statement(s): Not classified in accordance with international standards for workplace safety.

Precautionary Statement(s): None.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. **Composition/Information on Ingredients**

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Tranexamic Acid	1197-18-8	trans -4-(Aminomethyl)cyclohexanecarboxylic acid	C ₈ H ₁₅ NO ₂	157.2	10%

*The formula also contains Water for Injection that has a pH of 6.5 to 8.0.

4. First Aid Measures

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation: Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders: Use personal protective equipment (see section 8).

Signs and Symptoms: For information on potential signs and symptoms of exposure, see Section 2 – Hazards Identification and/or Section 11 – Toxicological Information.

Medical Conditions Aggravated by Exposure: None known.

Notes to Physician: None.

5. Firefighting Measures

Suitable Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam or water.

Unsuitable Extinguishing Media: Not determined.

SDS: Tranexamic Acid Injection 1000 mg/10 mL

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Other Specific Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

**Special Protective Equipment/
Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Pick up in the most efficient manner. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Environmental Precautions: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage,
Including Any Incompatibilities:** Store in a cool, dry place away from light. Store according to label and/or product insert information.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Tranexamic Acid	Pfizer OEL: 1500µg/m ³ , 8 Hour TWA

SDS: Tranexamic Acid Injection 1000 mg/10 mL

Engineering Controls:	Engineering controls should be used as the primary means to control exposures.
Respiratory Protection:	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Eyes Protection:	Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Hand Protection:	Not required for the normal use of this product. Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Aqueous colorless solution.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	6.5 – 8.0.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	No data available.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity: No data available.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static discharge, shock, or vibration): Heat and light.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition Products: No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: No data available.
Ingestion: No data available.
Skin Contact: May cause skin irritation.
Eye Contact: May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Tranexamic Acid	Rat	Oral	LD ₅₀	>10,000 mg/kg
Tranexamic Acid	Mouse	Oral	LD ₅₀	>10,000 mg/kg
Tranexamic Acid	Rat	Intravenous	LD ₅₀	1,330 mg/kg
Tranexamic Acid	Mouse	Intravenous	LD ₅₀	1,350 mg/kg
Tranexamic Acid	Rat	Subcutaneous	LD ₅₀	4,620 mg/kg

Repeated Dose Toxicity:

Compound	Species	Route	Type	Dose	Duration	Target Organ
Tranexamic Acid	Rat	Oral	LOAEL	4,000 mg/kg/d	6 Month(s)	Gastrointestinal system, Spleen

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Reproduction & Development Toxicity:

Compound	Study Type	Species	Route	End Point	Dose	Effect(s)
Tranexamic Acid	Embryo/Fetal Development	Rat	Oral	NOAEL	300 mg/kg/d	Not Teratogenic
Tranexamic Acid	Embryo/Fetal Development	Mouse	Oral	NOAEL	300 mg/kg/d	Not Teratogenic
Tranexamic Acid	Reproductive & Fertility	Rat, Rabbit, Mouse	No route specified	No end point specified	No dose specified	No effects at Maximum dose
Tranexamic Acid	Carcinogenicity	Mouse	Oral	LOAEL	5 g/kg/d	Immune system and Bone marrow

Genetic Toxicity:

Compound	Study Type	Cell Type/Organism	Results
Tranexamic Acid	<i>In Vivo</i>	Not specified	Negative
Tranexamic Acid	<i>In Vitro</i>	Not specified	Negative

Carcinogenicity:

Compound	Species	Route	End Point	Dose	Duration	Target Organ
Tranexamic Acid	Mouse	Oral	LOAEL	5 mg/kg/d	Not specified	Immune system and Bone marrow

Acute Toxicity – Dermal:

No data available.

Acute Toxicity – Inhalation:

No data available.

Corrosivity:

No data available.

Dermal Irritation:

No data available.

Eye Irritation:

No data available.

Sensitization:

No data available.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

No data available.

Reproductive Effects:

No data available.

Carcinogenicity:

None.

National Toxicology Program (NTP):

Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC):

Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA):

Not considered to be a carcinogen.

Mutagenicity:

No data available.

Aspiration Hazard:

Based on available data, the classification criteria are not met.

12. **Ecological Information**

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity

Aquatic: No data available.
Terrestrial: No data available.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No data available.
Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

13. **Disposal Considerations**

Dispose of all waste in accordance with Federal, State and Local regulations.

14. **Transport Information**

UN Number: Not applicable.
UN Proper Shipping Name: Not applicable.
Transport Hazard Class(es): Not applicable.
Packing Group: Not applicable.

Department of Transportation: Not regulated as a hazardous material.

International Air Transport Association (IATA): Not regulated as a dangerous good.

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

15. **Regulatory Information**

US Federal Regulations:

Toxic Substance Control Act (TSCA): Not listed.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

California Proposition 65: Not listed.

16. Other Information

Not made with natural rubber latex.

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