

## SAFETY DATA SHEET

### Tranexamic Acid Injection

#### Section 1: Identification

<b>Distributor</b>	Methapharm, Inc. 11772 West Sample Road, Suite 101 Coral Springs, FL, 33065 USA Tel: 954.341.0795 / 888.431.4276 Fax: 954.341.3588 / 866.265.2174 sales@methapharm.com www.methapharm.com
<b>Product Identifier:</b>	Tranexamic Acid for Injection
<b>Product Form:</b>	Mixture
<b>Container Information</b>	Vial
<b>Synonyms:</b>	Tranexamic Acid, Cyklokapron
<b>CAS Number:</b>	1197-18-8
<b>Chemical Name:</b>	trans -4-(Aminomethyl)cyclohexanecarboxylic acid.
<b>Chemical Family:</b>	Antifibrinolytic Agent.
<b>Recommended use:</b>	Pharmaceutical product used as blood clotting agent, Injectable.
<b>Product Type:</b>	Regulated Prescription Drug.

#### Section 2: Hazard(s) Identification

<b>Physical:</b>	Not classified.
<b>Health Hazards (GHS-US)</b>	Skin irritation Category 2 - H315 Eye irritation Category 2A - H319
<b>OSHA Hazard (s):</b>	Not classified.
<b>Appearance:</b>	Colorless solution.
<b>Hazard Pictograms (GHS-US)</b>	



GHS07

<b>Signal Word (GHS-US)</b>	Warning
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**Section 2: Hazard(s) Identification**

<b>Hazard Statement (GHS-US):</b>	H-315 – Causes skin irritation H319 – Causes serious eye irritation
<b>Precautionary Statements:</b>	P264 - Wash hands, forearms, and other exposed areas thoroughly after handling. P264 - Wash hands, forearms, and other exposed areas thoroughly after handling. P302+P352 - If on skin: Wash with plenty of water. P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321 - Specific treatment (see section 4 on this SDS). P332+P313 - If skin irritation occurs: Get medical advice/attention P337+P313 - If eye irritation persists: Get medical advice/attention. P362 - Take off contaminated clothing and wash it
<b>Additional Hazard Information:</b>	May cause eye irritation; Not acutely toxic (based on animal data). May produce allergic reactions after systemic administration.
<b>Known Clinical Effects:</b>	Adverse effects most commonly reported in clinical use include skin rash and gastrointestinal disturbances. Effects on blood and blood-forming organs have also occurred. Effects on vision have been seen during clinical use.
<b>Unknown Acute Toxicity (GHS-US)</b>	No data available

**Section 3: Composition/information on ingredients**

Chemical Name	Common Name	% Composition	CAS No.
trans -4-(Aminomethyl)cyclohexanecarboxylic acid.	Tranexamic Acid	10%	1197-18-8

\*The formula also contains water for injection that has a pH of 6.5 to 8.0.

**Section 4: First Aid Measures**

<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Skin Contact:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Eye contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Ingestion:</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Section 4: First Aid Measures**

<b>Injection:</b>	In cases of accidental injection, wash and disinfect area, seek medical attention.
<b>Most important symptoms/effects, acute and delayed:</b>	<p>Symptoms/Injuries: Causes irritation.</p> <p>Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.</p> <p>Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.</p> <p>Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.</p> <p>Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.</p> <p>Chronic Symptoms: None known.</p>
<b>Indication of immediate medical attention and special treatment needed:</b>	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**

<b>Suitable extinguishing media:</b>	Extinguish fires with CO2, extinguishing powder, foam, or water.
<b>Unsuitable extinguishing media:</b>	None known.
<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire
<b>Special protective equipment and precautions for firefighters:</b>	Wear self-contained breathing apparatus and full and protective gear.

**Section 6: Accidental release measures**

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure
<b>Measures for Cleaning / Collecting</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

**Section 7: Handling and Storage**
**General Handling**

Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

**Storage Conditions**

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F).

**Section 8: Exposure controls/personal protection**
**Exposure Limits:**

Compound	Issuer	Type	Exposure Limit
Tranexamic Acid	OSHA	TLV	Not Established
	ACGIH	PEL	Not Established
	-----	STEL	Not Established

**Appropriate engineering controls:**

Engineering controls should be used as the primary means to control exposures.

**Personal Protective Equipment:**

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:**

Not required for the normal use of this product. Wear Protective gloves when working with large quantities.

**Eyes:**

Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

**Skin:**

Not required for the normal use of this product. Wear protective clothing when working with large quantities.

**Respiratory protection:**

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposure to below the OEL.

**Section 9: Physical/Chemical Properties**

<b>Appearance (physical state, color, etc.)</b>	Colorless liquid
<b>Upper/lower flammability or explosive limits</b>	No data available
<b>Odor</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Odor threshold</b>	No data available
<b>Vapor density</b>	No data available
<b>pH</b>	6.5-8.0
<b>Relative density</b>	No data available
<b>Melting point</b>	No data available
<b>Solubility (ies)</b>	Soluble in water
<b>Initial boiling point</b>	No data available
<b>Flash point</b>	No data available
<b>Evaporation rate</b>	No data available
<b>Flammability</b>	No data available
<b>Partition coefficient: n-octanol/water</b>	No data available
<b>Auto-ignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Viscosity</b>	No data available

**Other information:**

<b>Chemical Family:</b>	Antifibrinolytic Agent, Mixture
<b>Molecular formula:</b>	Mixture
<b>Molecular weight:</b>	Mixture
<b>Solubility (other):</b>	No data available

**Section 10: Stability and reactivity**

<b>Reactivity:</b>	No specific test data related to reactivity available for this product.
<b>Chemical stability:</b>	Stable under normal conditions of use
<b>Possibility of hazardous reactions:</b>	None known.
<b>Conditions to avoid:</b>	Heat and light.
<b>Incompatible materials:</b>	As a precautionary measure, keep away from strong oxidizers.
<b>Hazardous decomposition products:</b>	No data available

**Section 11: Toxicological information**

**Information on likely routes of exposure:**

Not known.

**Symptoms related to the physical, chemical, and toxicological characteristics:**

May cause skin and eye irritation.

**Delayed, immediate or chronic effects of exposure:**

Not Available.

**Acute toxicity: (Species, Route, End Point, Dose)**  
**Product: Tranexamic Acid**

Rat - Oral LD50 >10,000mg/kg  
Mouse - Oral LD50 >10,000 mg/kg  
Rat - Intravenous LD50 1,330 mg/kg  
Mouse - Intravenous LD50 1,350 mg/kg  
Rat - Subcutaneous LD50 4,620 mg/kg

**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.

**Carcinogen Status:**

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

**Reproductive toxicity:**

Not teratogenic. No effects at maximum dose.

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

6 Months Rat Oral 4,000 mg/kg/day LOAEL  
Gastrointestinal system, Spleen

**Section 12: Ecological information**

**Ecotoxicity:**

The environmental characteristics of this mixture have not been fully evaluated. Release to the environment should be avoided.

**Persistence and degradability:**

Not available.

**Bioaccumulative potential:**

Not available.

**Mobility in soil:**

Not available.

**Other adverse effects:**

Not available.

### Section 13: Disposal considerations

**Disposal instructions:**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### Section 14: Transport information

**DOT:** Not regulated for transport  
**IATA:** Not regulated for transport  
**IMDG:** Not regulated for transport  
**EUADR:** Not regulated for transport

### Section 15: Regulatory information

**US federal regulations:**

<b>TSCA</b>	Not listed
<b>CERCLA</b>	Not on this list
<b>SARA 302</b>	Not on this list.
<b>SARA 304</b>	Not regulated
<b>SARA 313</b>	Not on this list

**OSHA Label:** Non-hazardous in accordance with international standards for workplace safety.

**Canada - WHMIS: Classifications** None required  
**WHMIS hazard class:** This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

**Tranexamic Acid** Schedule 4  
**Standard for Uniform Scheduling**  
**for Drug and Poisons:** 214-818-2  
**EU EINECS/ELINCS list**

**Water**  
**Inventory-USA TSCA- Sect.8(b)** Present  
**Australia (AICS):** Present  
**REACH – Annex IV- Exemptions** Present  
**from the obligations of Register:**  
**EU EINECS/ELINCS list** 231-791-2

**Section 16: Other information**

**Issue date:** 04-05-2019

**Revision date:** N/A

**Version #:** 01

**Further information:** Not available.

**Disclaimer:** Methapharm, Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**Revision Information:** Not applicable