

SAFETY DATA SHEET
Tranexamic Acid Injection, USP



Caplin Steriles Limited

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name : Tranexamic Acid Injection, USP (Caplin Steriles Ltd.)

Chemical Family : Mixture

Intended Use: : Pharmaceutical product used as blood clotting agent

Manufacturer or Supplier's Details : Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.

Details of the Supplier of the Safety Data Sheet

Emergency Telephone Number : +91-4467901901/02/03

SECTION 2: HAZARDS IDENTIFICATION

Appearance : Colorless solution.

Statement of Hazard : Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information

Short Term : May cause eye irritation; Not acutely toxic (based on animal data). May produce allergic reactions after systemic administration.
: 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.

Known Clinical Effects

EU Indication of danger : Not classified.

Australian Hazard Classification (NOHSC) : Non-Hazardous Substance. Non-Dangerous Goods.

Note : This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Tranexamic Acid	1197-18-8	214-818-2	Not Listed	10
Water, purified	7732-18-5	231-791-2	Not Listed	*

SAFETY DATA SHEET
Tranexamic Acid Injection, USP



Caplin Steriles Limited

Additional Information : * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

SECTION 4: FIRST AID MEASURES

Eye Contact : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact : Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Inhalation : Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Ingestion : 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.

Symptoms and Effects of Exposure : For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing Media : Use carbon dioxide, dry chemical, or water spray.

Hazardous combustion products : Carbon monoxide, carbon dioxide, and oxides of nitrogen may be generated in a fire.

Fire Fighting Procedures : During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards : Not applicable.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions : Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting : Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

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.

SAFETY DATA SHEET
Tranexamic Acid Injection, USP



Caplin Steriles Limited

SECTION 7: HANDLING AND STORAGE

- General Handling** : Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.
- Storage Conditions** : Store in a cool, dry place away from light.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Tranexamic Acid

OEL TWA-8 Hr : 1500µg/m³ 474 mg/m³

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

- Engineering Controls** : Engineering controls should be used as the primary means to control exposures.
- Environmental Exposure Controls** : Refer to specific Member State legislation for requirements under Community environmental legislation
- 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 exposures to below the OEL.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

- Physical State** : Aqueous solution
- Color** : Colorless
- Odor** : No data available.
- Odor Threshold** : No data available.
- Molecular Formula** : Mixture
- Molecular Weight** : Mixture
- Solvent Solubility** : No data available.
- Water Solubility** : No data available.
- pH** : 6.5 – 8.0
- Melting/Freezing Point (°C)** : No data available.
- Boiling Point (°C)** : No data available.
- Partition Coefficient: (Method, pH, Endpoint, Value)**
- Tranexamic Acid** : No data available.

Tranexamic Acid Injection, USP
Revision date: March 06, 2024

SAFETY DATA SHEET
Tranexamic Acid Injection, USP



Caplin Steriles Limited

Water, purified	: No data available.
Decomposition Temperature (°C)	: No data available.
Evaporation Rate (Gram/s)	: No data available.
Vapour Pressure	: No data available.
Vapor Density	: No data available.
Relative Density	: No data available.
Viscosity	: No data available.
Flammability	
Auto ignition Temperature (Solid) (°C)	: No data available.
Flammability (Solids)	: No data available.
Flash Point (Liquid) (°C)	: No data available.
Upper Explosive Limits (Liquid) (% by Vol.)	: No data available.
Lower Explosive Limits (Liquid) (% by Vol.)	: No data available.

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability	: Stable under normal conditions of use.
Conditions to Avoid	: Heat and light
Incompatible Materials	: As a precautionary measure, keep away from strong oxidizers

SECTION 11: TOXICOLOGICAL INFORMATION

General Information : The information included in this section describes the potential hazards of the active ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

	Rat Oral LD 50 >10,000 mg/kg
	Mouse Oral LD 50 >10,000 mg/kg
Tranexamic Acid	: Rat Intravenous LD 50 1,330 mg/kg
	Mouse Intravenous LD 50 1,350 mg/kg
	Rat Subcutaneous LD 50 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.

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

Tranexamic Acid : 6 Month(s) Rat Oral 4,000 mg/kg/day LOAEL Gastrointestinal system, Spleen

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

	Embryo / Fetal Development Rat Oral 300 mg/kg/day NOAEL Not teratogenic
Tranexamic Acid	: Embryo / Fetal Development Mouse Oral 300 mg/kg/day NOAEL Not Teratogenic
	Reproductive & Fertility Rat Rabbit Mouse No route specified No effects at maximum dose

SAFETY DATA SHEET
Tranexamic Acid Injection, USP



Caplin Steriles Limited

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Tranexamic Acid : *In Vivo* Not specified Negative
In Vitro Not specified Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Tranexamic Acid : Not specified Mouse Oral 5 g/kg/day LOAEL Immune system, Bone marrow

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

SECTION 12: ECOLOGICAL INFORMATION

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

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Treatment Methods : 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

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15: REGULATORY INFORMATION

OSHA Label	:	Non-hazardous in accordance with international standards for workplace safety.
<u>Canada - WHMIS: Classifications</u>		
WHMIS hazard class	:	None required This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.
Tranexamic Acid	:	
Standard for the Uniform Scheduling for Drugs and Poisons:	:	Schedule 4
EU EINECS/ELINCS List	:	214-818-2

SAFETY DATA SHEET
Tranexamic Acid Injection, USP



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Water, purified	:	
Inventory - United States TSCA - Sect. 8(b)	:	Present
Australia (AICS)	:	Present
REACH - Annex IV - Exemptions from the obligations of Register:	:	Present
EU EINECS/ELINCS List	:	231-791-2

SECTION 16: ADDITIONAL INFORMATION

Data Sources: : Publicly available toxicity information.

SDS Creation Date : July 23, 2017

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Version : 01

Prepared by : Caplin Steriles Limited

Disclaimer : The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Caplin Steriles assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

. ----End of Safety Data Sheet----