

**SAFETY DATA SHEET**  
**Tranexamic Acid Injection, 100 mg/mL**



**SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**

**1.1. Product identifier**

**Product Name** : Tranexamic Acid Injection

**Chemical Family** : Mixture

**Synonyms** : Tranexamic Acid

**1.2. Relevant identified uses of the substance or mixture and uses advised**

**Recommended use** : Pharmaceutical product used as blood clotting agent.

**1.3. Details of the supplier of the safety data sheet**

**Details of the Supplier of the Safety Data Sheet** : Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.

**1.4 Emergency Telephone Number**

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

**SECTION 2: HAZARDS IDENTIFICATION**

**2.1 Classification of the Substance or Mixture**

Not classified as hazardous

**2.2 Label elements**

**Signal word** Not Classified

**Hazard statements** Not classified in accordance with international standards for workplace safety

**2.3 Other Hazards**

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8)

**Note** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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 INGREDIENT**

**3.1 Substances**

**Substances** Not applicable

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### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Tranexamic Acid 1197-18-8	10	-	214-818-2	No data available	Not Listed	No data available	No data available

#### Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water 7732-18-5	Q.S. to 100 %	-	231-791-2	No data available	Not Listed	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

#### Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 – 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 – 4 hour - gas - ppm
Water 7732-18-5	Q.S. to 100 %	No data available	No data available	No data available	No data available

**Additional information:** 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

### 4.1 Description of First Aid Measures

**Inhalation:** Remove to fresh air. Seek immediate medical attention/advice.

**Eye Contact:** Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

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

**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.

**4.2 Most Important Symptoms and Effects, Both Acute and Delayed**

**Most important symptoms and effects** For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

**4.3 Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physicians** None.

**SECTION 5: FIRE FIGHTING MEASURES**

**5.1 Extinguishing media:**

**Suitable Extinguishing media** Dry chemical, CO<sub>2</sub>, alcohol-resistant foam or water spray.

**5.2 Special Hazards Arising from the Substance or Mixture**

**Specific hazards arising from the chemical** Fine particles (such as dust and mists) may fuel fires/explosions

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

**5.3 Advice for Fire-Fighters**

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

**6.1 Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**For emergency responders** Use personal protection recommended in Section 8.

**6.2. Environmental precautions**

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

**6.3 Methods and Material for Containment and Cleaning Up**

**Methods for containment:** Keep away from incompatible materials.

**Methods for cleaning** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Prevention of secondary hazards:** Clean contaminated objects and areas thoroughly observing environmental regulations.

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**6.4 Reference to other sections**

**Reference to other sections**

See section 8 for more information. See section 13 for more information.

**SECTION 7: HANDLING AND STORAGE**

**7.1 Precautions for Safe Handling**

**Advice on safe handling**

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

**7.2 Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store in a cool, dry place away from light. Store as directed by product packaging.

**7.3. Specific end use(s)**

**Specific end use(s):** Pharmaceutical drug product

**SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION**

**8.1 Control Parameters**

**Tranexamic Acid**

Pfizer OEL TWA-8 Hr: 1000 µg/m<sup>3</sup>

**8.2 Exposure Controls**

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Environmental exposure controls** No information available.

**Personal protective equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Eye/face protection** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

**Hand protection** Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must

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	meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).
<b>Skin and body protection</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
<b>Respiratory protection:</b>	Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<b>Physical State:</b>	Aqueous solution
<b>Color</b>	Colourless
<b>Odor Threshold:</b>	No information available.
<b>Molecular Weight:</b>	Mixture
<b>Odor:</b>	No information available.
<b>Molecular Formula:</b>	Mixture

<u>Property</u>	<u>Values</u>
<b>pH</b>	6.5 - 8.0
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	No data available
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available

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**Decomposition**

**temperature** No data available

**Kinematic viscosity** No data available

**Dynamic viscosity** No data available

**Particle characteristics**

**Particle Size** No information available

**Particle Size Distribution** No information available

**Explosive properties** No information available

**9.2. Other information**

No information available

**9.2.1. Information with regard to physical hazard classes**

No information available

**9.2.2. Other safety characteristics**

No information available

**SECTION 10: STABILITY AND REACTIVITY**

**10.1. Reactivity**

**Reactivity:** No data available

**10.2. Chemical stability**

**Stability:** Stable under normal conditions.

**Explosion data**

**Sensitivity to Mechanical impact** No data available

**Sensitivity to Static Discharge** No data available

**10.3. Possibility of hazardous reactions**

**Possibility of Hazardous Reactions** No information available.

**10.4. Conditions to avoid**

**Conditions to Avoid:** Heat and light.

**10.5. Incompatible materials**

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

**10.6. Hazardous decomposition products**

**Hazardous Decomposition**

**Products:** No data available.

**SECTION 11: TOXICOLOGICAL INFORMATION**

**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

**General Information:** The information included in this section describes the potential hazards of the individual ingredients

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**Short term**

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

**Known Clinical Effects:**

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.

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

**Tranexamic Acid**

Rat Oral LD50 >10,000 mg/kg  
Mouse Oral LD50 >10,000 mg/kg  
Rat IV LD50 1,330 mg/kg  
Mouse IV LD 50 1,350 mg/kg  
Rat Subcutaneous LD 50 4,620 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-

**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 & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

**Tranexamic Acid**

Embryo / Fetal Development Rat Oral 300 mg/kg/day NOAEL Not teratogenic  
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

**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 Bone marrow, Immune system

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

**11.2 Information on other hazards**

**11.2.1 Endocrine disrupting properties**

**Endocrine disrupting properties** No information available.

**11.2.2 Other information**

**Other adverse effects** No information available.

## SECTION 12: ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

**12.1 Toxicity:** No information available.

**12.2 Persistence and Degradability:**

**Persistence and Degradability:** No information available.

**12.3. Bioaccumulative potential**

**Bioaccumulation:** No information available.

**12.4. Mobility in soil**

**Mobility in Soil:** No information available.

**12.5. Results of PBT and vPvB assessment**

**PBT and vPvB assessment** No information available.

**12.6. Endocrine disrupting properties**

**Endocrine disrupting properties** No information available.

**12.7 Other adverse effects**

No information available

## SECTION 13: DISPOSAL CONSIDERATIONS

**13.1 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.



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**SECTION 15: REGULATORY INFORMATION**

**15.1 Safety, Health and Environmental regulations/Legislation Specific for the Substance or Mixture**

**Tranexamic Acid**

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	214-818-2
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4

**WATER FOR INJECTION**

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

**European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

**Authorizations and/or restrictions on use:**

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

**Persistent Organic Pollutants**

Not applicable

**Ozone-depleting substances (ODS) regulation (EC) 1005/2009**

Not applicable

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**15.2. Chemical safety assessment**

**Chemical Safety Report** No information available

**SECTION 16: OTHER INFORMATION**

**Key or legend to abbreviations and acronyms used in the safety data sheet**

**Prepared by** : Caplin Steriles Limited

**Data Sources:** Publicly available toxicity information. Caplin proprietary drug development information.

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**General Disclaimer:** The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

**---End of Safety Data Sheet---**