

Section 1: IDENTIFICATION OF SUBSTANCE AND SOCIETY

1.1. Identification of the substance

Product form: Sterile solution for intravenous Injection.

Product name: Tranexamic acid injection, USP.

Chemical name: Trans-4-(aminomethyl)cyclohexanecarboxylic acid.

Synonym: None

National Drug Code (NDC): 81284-611-00 (Provepharm) ; 81284-612-00 (NovaPlus).

Trade name: Not applicable.

Molecular formula: C₈H₁₅NO₂.

CAS No.: 1197-18-8.

EC No.: Not applicable.

REACH No.: Not applicable

1.2. Uses

Pharmaceutical. As a blood clotting agent.

1.3. Information about the security data sheet provider

Company	Supplier	Distributor
Provepharm SAS 22 Rue Marc Donadille 13013 Marseille, France Phones: 04 91 08 69 30 Website: www.provepharm.com Email: hse@provepharm.com	Immaculé Lifesciences LTD India Vill.Thanthewal, Ropar Road, Nalagarh, Dist. Solan, (H.P.)-174101 India	Provepharm Inc. 100 Springhouse drive, Suite 105, Collegeville, PA 19426, USA Phone: +1 610 601 8600

1.4. Emergency telephone number:

CHEMTREC: 1-800-424-9300 (within USA and Canada), +1 703-527-3887 (outside USA and Canada).

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or the mixture

Potential Acute Health Effects: Hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects: Not available.

Carcinogenic Effects: Not available.

Teratogenic Effects: Not available.

Developmental Toxicity: Repeated or prolonged exposure is not known to aggravate medical conditions.

Adverse effects: Not available.

2.2. Label elements

Warning mention: Not applicable.

Hazard statements: Not applicable.

Precautionary statements: Not applicable.



2.3. Other hazards

Not available.

2.4. Unknown acute toxicity

Not applicable.

Section 3: COMPOSITION/INFORMATIONS ON THE SUBSTANCE

3.1. Substances

Name	Product identifier	%	Classification
Tranexamic acid	Cas-No.: 1197-18-8 Molecular Weight: 157.21 g/mole	10	Not applicable

3.2. Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1. Description of 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.

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

After 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.

After 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.

After ingestion: Ingestion may cause adverse effects.

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

4.2. Most important symptoms and effects, both acute and delayed

Not available.

4.3. Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: Small fire: Use dry chemical powder. Large fire: Use water spray, fog or foam.

Unsuitable extinguishing media: Do not use water jet.

5.2. Special hazards arising from the substance or mixture

Fire or explosion hazard: Not considered flammable but may burn at high temperatures. A pressure increase will occur and the container may burst.

Combustion Products: Decomposition products may include carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂).

5.3. Advice for firefighters

Protective equipment & precautions for firefighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.



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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear appropriate protecting clothing and equipment as described in section 8. Ventilate the area. Eliminate all ignition sources.

6.2. Environmental precautions

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3. Methods and material for containment and cleaning up

Small spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water and soap on the contaminated spill site.

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.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe 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.

7.2. Conditions for safe storage, including any incompatibilities

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.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limit: Not available.

8.2. Exposure controls

Appropriate 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 generate fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Hand protection: Nitrile or latex gloves (EN 374).

Eye protection: Wear splash goggles (EN 366).

Skin and body protection: Wear suitable working clothes.

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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES



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9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Appearance:	No data available
Color:	Colorless
Odor:	Mild
Odor threshold:	No data available
pH:	6.5 – 8.0
Melting point:	No data available
Freezing point:	No data available
Boiling point:	100°C (212°F)
Flash point:	No data available
Relative evaporation rate (butyl acetate=1):	No data available
Flammability (solid, gas):	No data available
Vapor pressure:	No data available
Relative vapor density at 20 °C:	No data available
Relative density:	No data available
Solubility:	Easily soluble in cold water
Partition coefficient n-octanol/water (Log Pow):	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosion limits:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available

9.2. Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

The product is reactive with oxidizing agents.

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Not available.

10.4. Conditions to avoid

Excess heat and oxidizing agents.

10.5. Incompatible materials

Reactive with oxidizing agents.

10.6. Hazardous decomposition products

Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION



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11.1. Information on toxicological effects

Acute toxicity:

LD50 (oral), rat:	>10,000 mg/kg
LD50 (oral), mouse:	>10,000 mg/kg
LD50 (intravenous), rat:	2260 mg/kg
TDLo (intravenous), woman:	2180 mg/kg, 6 days
TDLo (intramuscular), woman:	960 mg/kg, 3 days
LD50 (intraperitoneal), mice:	9770 mg/kg
LD50 (subcutaneous), mice:	>10 g/kg
LD50 (intravenous), mice:	4900 mg/kg
LD50 (intravenous), dog:	>6 g/kg

Routes of exposure: Inhalation and ingestion.

Carcinogenic/mutagenic/toxic effects for reproduction: 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.

Specific target organ toxicity – single exposure: Not available.

Specific target organ toxicity – repeated exposure: Not available.

Aspiration hazard: Not available.

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

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

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Not available.

12.2. Persistence and degradability

Possibly hazardous short-term degradation products are not likely. However, long term degradation products may arise. The product itself and its products of degradation are not toxic

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

12.5. Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste classification: Not available.

Advice on disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

Waste disposal number of waste from residues/unused products : Dispose of waste in accordance with federal, state and local environment control regulations.

Contaminated packaging: Empty containers should be taken for local recycling, recovery or waste disposal. Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of like the product.



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SECTION 14: TRANSPORT INFORMATION

The listed CAS ingredient(s) in this final formula for finished goods are not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Department of Transportation (DOT) Classification:

UN Number: Not regulated.

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

15.1. Federal and State Regulations

TSCA 8(b) inventory: no products found.

15.2. 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: OTHER INFORMATION

None.