SAFETY DATA SHEET



1. Identification

Product identifier Tranexamic acid

Other means of identification

Catalog number 1672745 **CAS** number 1197-18-8

Chemical name trans-4-(Aminomethyl)cyclohexanecarboxylic acid

Recommended use For analytical laboratory use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

U. S. Pharmacopeia Company name **Address** 12601 Twinbrook Parkway

> Rockville MD 20852-1790 **United States**

Customer Service

Telephone 301-881-0666

www.usp.org Website E-mail RSTECH@usp.org

CHEMTREC within US & **Emergency phone number** 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified. **Health hazards** Not classified. **Environmental hazards** Not classified. **OSHA** defined hazards Not classified.

Label elements

Hazard symbol None. Signal word None.

Hazard statement Not available.

Precautionary statement

Prevention Not available. Not available. Response Storage Not available. Not available. **Disposal** Hazard(s) not otherwise None known.

classified (HNOC)

Supplemental information Pharmacologically active material.

3. Composition/information on ingredients

Substance

| Chemical name | Common name and synonyms | CAS number | % |
|-----------------|--------------------------|------------|-----|
| Tranexamic acid | | 1197-18-8 | 100 |

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

4. First-aid measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

Call a physician if symptoms develop or persist.

Skin contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Rinse with water. Get medical attention if irritation develops and persists. Eve contact

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Ingestion

Most important

symptoms/effects, acute and

delayed

Pharmacologically active material. Occupational exposure may cause physiological effects.

Indication of immediate medical attention and special

treatment needed **General information** Provide general supportive measures and treat symptomatically.

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 exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must

5. Fire-fighting measures

Suitable extinguishing media Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

receive immediate medical attention.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire fighting

Specific methods

equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing equipment and protective clothing.

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists. and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage. including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use

 Material
 Type
 Value

 Tranexamic acid (CAS
 TWA
 1.5 mg/m3

1197-18-8)

Biological limit valuesNo biological exposure limits noted for the ingredient(s).

Appropriate engineering

controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary.

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

Hand protection Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved

or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of

skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection Respirators are generally not required for laboratory operations. Use a tight-fitting full-face

respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task

and the level of existing engineering controls.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of USP materials.

Pharmacological effects may be seen with occupational exposure.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.

Form Crystalline powder.
Color White. Beige.
Odor Odorless.
Odor threshold Not available.

pH Not available.

Melting point/freezing point 726.8 - 737.6 °F (386 - 392 °C) (decomposes)

Initial boiling point and boiling

range

Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit James Net

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

(%)

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure < 0.0000001 kPa (77 °F (25 °C))

Vapor density 5.4

Relative density Not available.

Solubility(ies)

Solubility (water) Soluble.

Solubility (other) Ethanol: Slightly soluble.

Material name: Tranexamic acid usp sps us

Ether: Slightly soluble. Glacial acetic acid: Soluble.

Most organic solvents: Practically insoluble.

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Molecular formula C8H15NO2 Molecular weight 157.21

pH in aqueous solution 6.5 - 7.5 Solution: 5%

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoidContact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.Eye contactKnowledge about health hazard is incomplete.IngestionKnowledge about health hazard is incomplete.

Symptoms related to the physical, chemical and toxicological characteristics

Skin rash. Visual disturbances. Dizziness. Headache. Tiredness. Shortness of breath. Chest pain.

Slurred speech. Numbness of extremities. Gastrointestinal disturbances. Loss of appetite.

Information on toxicological effects

Acute toxicity

| Product | Species | Test Results |
|---------------------------------|---------|--------------|
| Tranexamic acid (CAS 1197-18-8) | | |
| <u>Acute</u> | | |
| Oral | | |

LD50 Mouse > 15 g/kg

Rat > 15 g/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

irritation

Local effects

Bovine Corneal Opacity and Permeability Test Method

Result: Not corrosive.

Reconstructed Human Epidermis Test

Result: Negative.

Respiratory or skin sensitization

Respiratory sensitizationKnowledge about health hazard is incomplete.
Skin sensitization
Knowledge about health hazard is incomplete.

In Vitro ARE-Nrf2 luciferase KeratinoSens

Result: Negative.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete. **Carcinogenicity** Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicityKnowledge about health hazard is incomplete.

Reproductivity

1500 mg/kg/day Reproductivity study

Result: Negative: No adverse effects in offspring of rats or

mice.

Species: Rodent

Specific target organ toxicity -

Knowledge about health hazard is incomplete.

single exposure

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

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

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this substance.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructionsDispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

shipment.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard

Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Nο

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | Yes |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | Yes |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | Yes |
| Korea | Existing Chemicals List (ECL) | Yes |
| New Zealand | New Zealand Inventory | Yes |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | Yes |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | Yes |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

^{*}A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

 Issue date
 07-21-2006

 Revision date
 04-13-2023

Version # 04

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

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