## Section 1 - Identification

**(a) Product Identifier:** Tranexamic Acid in 0.7% Sodium Chloride Injection

**(b) Product Code:** 83634-403-51; 83634-403-82

**Common/Trade Name:** NA

**Chemical Name:** trans-4-(aminomethyl)cyclohexanecarboxylic acid

**Chemical Family:** Antifibrinolytic Agent

**(c) Product Use:** Pharmaceutical, Injectable

**Product Type:** Regulated Prescription Drug

**Container Information:** Vial

**(d) Distributor:** Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL 60173, 847-773-4901

**(e) Emergency Telephone:** 855-283-6229

## Section 2 - Hazards Identification

**(a) Classification:** Not classified as hazardous.

| **(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):** | **(c) Description of Hazards:** |
|---|---|
| **Signal Word:** | None. |
| **Hazard Statements:** | Not classified in accordance with international standards for workplace safety. |
| **Precautionary Statements:** | None. |

**(d) Unknown Acute Toxicity** N/A

## Section 3 – Composition / Information on Ingredients

| (a) Chemical Name | (b) Common Name / Synonym | % Composition or other measure | (c) CAS No. | (d) Impurities / Stabilizing Additives |
|---|---|---|---|---|
| trans-4-(aminomethyl) cyclohexanecarboxylic acid | Tranexamic Acid | 10 mg/mL | 1197-18-8 | N/A |
| Sodium Chloride | Sodium Chloride | 7 mg/mL | 7647-14-5 | NA |

## Section 4 – First Aid Measures

**Eye Exposure:** If worn and easy to do, remove contact lenses. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

**Skin Exposure:** Wash exposed area with soap and water and remove contaminated clothing and/or shoes. If irritation occurs or persists, notify medical personnel and supervisor.

**Ingestion:** If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

**Inhalation:** Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

**Notes to physician:** Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.
Known symptoms or effects (if any) are described in Section 11 – Toxicological Information.

## Section 5 – Fire-fighting Measures

**(a) Extinguishing Media:** Use water spray (fog), foam, dry powder, or carbon dioxide as appropriate for surrounding fire and materials.

**(b) Hazardous Combustion Products:** No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, and other nitrogen-containing compounds.

**(c) Special Protective Equipment / Precautions:** In case of fire in the surroundings, use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

## Section 6 - Accidental Release Measures

**Spill:** Wear appropriate protective clothing to avoid exposure. Avoid dust formation and breathing dust. Ensure adequate ventilation.
Clean spill area thoroughly using HEPA filtered vacuum to sweep up dry solids, wet-brushing, or by absorbing spilled liquids.
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

**Release to Air:** Not available.

**Release to Water:** Do not empty into drains. Avoid release to the environment.

## Section 7 - Handling and Storage

**General Handling:** Avoid contact with skin and eyes. Use appropriate personal protective equipment when handling. Generation of dust or volatile vapors should be minimized.

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

## Section 8 - Exposure Controls / Personal Protection

### (a) Exposure Limits

| Compound | OSHA PEL (TWA) | ACGIH TLV (TWA) | NIOSH REL (TWA) |
|---|---|---|---|
| Tranexamic Acid | NE | NE | NE |
| Sodium Chloride | NE | NE | NE |

NE – Not Established

### (b) Engineering Controls

Use a laboratory fume hood or local exhaust ventilation to minimize airborne dust or volatile vapors when handling.

### (c) Individual Protection Measures

| | |
|---|---|
| Respiratory Protection: | Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. At a minimum, a tight-fitting full-face respirator with HEPA filter is required when performing dust-generating operations and for spill cleanup. |

| | |
|---|---|
| Eye 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: | Wear proper gowning appropriate to the task. Protective garments (coveralls, disposable coveralls, lab coats) are not to be worn in common areas (such as cafeterias) or out-of-doors. Employees must be trained in proper gowning and degowning practices. Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. |
| Other Protective Equipment: | Wash hands in the event of contact with this substance, especially before eating, drinking, or smoking. Protective equipment is not to be worn outside the work area (such as in common areas or out-of-doors). |
| Additional Exposure Precautions: | Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedure. |

## Section 9 - Physical and Chemical Properties

| | | |
|---|---|---|
| **(a)** | **Appearance** | Clear, colorless liquid |
| **(b)** | **Odor** | Not available |
| **(c)** | **Odor Threshold** | Not available |
| **(d)** | **pH** | 6.5-8.0 |
| **(e)** | **Melting Point:** | Not available |
| **(f)** | **Initial Boiling Point:** | Not available |
| **(g)** | **Flash Point** | Not available |
| **(h)** | **Evaporation Rate:** | Not available |
| **(i)** | **Flammability** | Not available |
| **(j)** | **Upper Lower Flammability or Explosion Limits** | Not available |
| **(k)** | **Vapor Pressure:** | Not available |
| **(l)** | **Vapor Density:** | Not available |
| **(m)** | **Relative Density** | Not available |
| **(n)** | **Solubility(ies)** | Not applicable |
| **(o)** | **Partition Coefficient: n-octanol/water** | Not available |
| **(p)** | **Auto-ignition Temperature** | Not available |
| **(q)** | **Decomposition Temperature** | Not available |

| | | |
|---|---|---|
| **(r)** | **Viscosity** | Not available |

## Section 10 - Stability and Reactivity

| | | |
|---|---|---|
| **(a)** | **Reactivity** | Contact with incompatible materials and exposure to heat. |
| **(b)** | **Chemical Stability** | The product is stable under normal conditions of use. |
| **(c)** | **Possibility of Hazardous Reactions** | None known. |
| **(d)** | **Conditions to Avoid** | Contact with incompatible materials and exposure to heat. |
| **(e)** | **Incompatible Materials** | Acids, bases, and oxidizers. |
| **(f)** | **Hazardous Decomposition Products** | None known. |

## Section 11 - Toxicological Information

| | | |
|---|---|---|
| **(a)** | **Likely Routes of Exposure** | All the formulation components may be absorbed by inhalation, ingestion, and skin and eye contact. |
| **(b)** | **Symptoms related to the physical, chemical and toxicological characteristics** | May cause skin and eye irritation. |
| **(c)** | **Delayed and immediate effects and also chronic effects from short and long term exposure** | None available. |

**(d) Acute Toxicity**

| Component | Type | Route | Species | Dosage |
|---|---|---|---|---|
| Tranexamic Acid | $LD_{50}$<br>$LD_{50}$<br>$LD_{50}$ | Oral<br>Oral<br>Oral | Rat<br>Mouse<br>Dog | >15,000 mg/kg<br>>10,000 mg/kg<br>>5,000 mg/kg |
| Sodium Chloride | $LD_{50}$<br>$LD_{50}$<br>$LD_{50}$ | Oral<br>Inhalation<br>Skin | Rat<br>Rat<br>Rabbit | 3,000 mg/kg<br>>42,000 mg/m$^3$/1hr<br>>10,000 mg/kg |

**(e) Hazardous Chemical Listings**

NTP: Not Listed IARC: Not Listed OSHA: Not Listed

## Section 12 - Ecological Information

| | | |
|---|---|---|
| **(a)** | **Ecotoxicity** | Tranexamic Acid: *Pseudokirchneriella subcapitata* $ErC_{50}$ of >100 mg/L (72 hours), *Daphnia magna* $EC_{50}$ of > 100 mg/L (24 hours and 48 hours).<br><br>Sodium Chloride: *Lepomis macrochirus* (Bluegill) $LC_{50}$ of 5.840 mg/L (96 hours), *Daphnia magna* (water flea) static test $EC_{50}$ of 874 mg/L (48 hours), *Daphnia magna* (water flea) static test $LC_{50}$ of 4.136 mg/L (48 hours), *Nitzschia* species static test $EC_{50}$ of 2.430 mg/L (120 hours), *Pimephales promelas* (fathead minnow) NOEC of 252 mg/L (33 days), *Daphnia pulex* (water flea) semi-static test NOEC of 314 mg/L (21 days). |
| **(b)** | **Persistence and degradability** | Not Available |
| **(c)** | **Bioaccumulative potential** | Not Available |
| **(d)** | **Mobility in soil** | Not Available |
| **(e)** | **Other Adverse Effects** | Not Available |

## Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

## Section 14 - Transport Information

**DOT**: Not regulated as a hazardous material.
**IATA**: Not regulated as a hazardous material.
**IMDG**: Not regulated as a hazardous material.

| | | |
|---|---|---|
| **(a)** | **UN Number** | Not Available |
| **(b)** | **UN Proper Shipping Name** | Not Available |
| **(c)** | **Transport Hazard Class(es)** | Not Available |
| **(d)** | **Packing Group** | Not Available |
| **(e)** | **Environmental Hazards** | Not Available |
| **(f)** | **Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)** | Not Available |
| **(g)** | **Special Precautions** | Avoid release to environment. |

## Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Avenacy usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**U.S. Regulations**:
TSCA: Sodium Chloride is listed (Domestic Substance List)
CERCLA - Not on this list
SARA 302 - Not on this list
SARA 304: Not regulated
SARA 313 - Not on this list

## Section 16 - Other Information

As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information
contact:

Avenacy
10 N. Martingale Road, Suite 225
Schaumburg, IL 60173
847-773-4901

**Glossary:** This glossary contains definitions of general terms used in Safety Data Sheets. Not all of these Glossary Terms will apply to this Safety Data Sheet (SDS).

| | |
|---|---|
| ACGIH | American Conference of Governmental Industrial Hygienists |
| AICS | Australian Inventory of Chemical Substances |
| AIHA | American Industrial Hygiene Association |
| ANSI | American National Standards Institute |
| CAS Number | Chemical Abstract Service Registry Number |
| CERCLA | Comprehensive Environmental Response Compensation and Liability Act (of |
| CHAN | Chemical Hazard Alert Notice |
| CHEMTREC | Chemical Transportation Emergency Center |
| DOT | Department of Transportation |
| DSL | Domestic Substances List |
| ECHA | European Chemicals Agency |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |
| EPA | Environmental Protection Agency |
| GHS | Globally Harmonized System of Classification and Labelling of Chemicals |

| | |
|---|---|
| HEPA | High Efficiency Particulate Air (Filter) |
| HMIS | Hazardous Materials Identification System |
| IARC | International Agency for Research on Cancer |
| ICAO/IATA | International Civil Aviation Organization/International Air Transport |
| IMO | International Maritime Organization |
| KOW | Octanol/Water Partition Coefficient |
| LEL | Lower Explosive Limit |
| MSDS | Material Safety Data Sheet |
| MSHA | Mine Safety and Health Administration |
| NA | Not Applicable, except in Section 14 where NA = North America |
| NE | Not Established |
| NADA | New Animal Drug Application |
| NAIF | No Applicable Information Found |
| NCI | National Cancer Institute |
| NDSL | Non-Domestic Substances List |
| NFPA | National Fire Protection Association |
| NIOSH | National Institute for Occupational Safety and Health |
| NPDES | National Pollutant Discharge Elimination System |
| NOS | Not Otherwise Specified |
| NTP | National Toxicology Program |
| OSHA | Occupational Safety and Health Administration |
| OEL | Occupational Exposure Limit |
| PEL | Permissible Exposure Limit (OSHA) |
| RCRA | Resource Conservation and Recovery Act |
| RQ | Reportable Quantity |
| RTECS | Registry of Toxic Effects of Chemical Substances |
| SARA | Superfund Amendments and Reauthorization Act |
| SDS | Safety Data Sheet |
| STEL | Short Term Exposure Limit |
| TLV | Threshold Limit Value (ACGIH) |
| TPQ | Threshold Planning Quantity |
| TSCA | Toxic Substances Control Act |
| TWA | Time Weighted Average/8 Hours Unless Otherwise Noted |
| UEL | Upper Explosive Limit |
| UN | United Nations |
| USP | United States Pharmacopeia |
| WEEL | Workplace Environmental Exposure Level (AIHA) |
| WHMIS | Workplace Hazardous Materials Information System |