

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Tranexamic Acid in Sodium Chloride Injection

### 1.2. Intended Use of the Product

Tranexamic Acid in Sodium Chloride Injection is indicated in patients with hemophilia for short-term use (two to eight days) to reduce or prevent hemorrhage and reduce the need for replacement therapy during and following tooth extraction.

### 1.3. Name, Address, and Telephone of the Responsible Party

#### Manufacturer/Distributor

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

<http://www.fresenius-kabi.com/us/>

### 1.4. Emergency Telephone Number

**Emergency Number** : VelocityEHS

(800)255-3924 (North America)

+1 (813)248-0585 (International)

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

#### GHS-US/CA Classification

Not classified.

### 2.2. Label Elements

#### GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

### 2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

### 2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	AQUA	(CAS-No.) 7732-18-5	98.3	Not classified.
Tranexamic acid	trans-4-Aminoethylcyclohexane-1-carboxylic acid trans-4-(Aminomethyl)cyclohexanecarboxylic acid trans-p-(Aminomethyl)cyclohexanecarboxylic acid trans-4-Aminomethyl-1-cyclohexanecarboxylic acid trans-4-Aminomethylcyclohexane-1-carboxylic acid trans-1-Aminomethylcyclohexane-4-carboxylic acid Cyclohexanecarboxylic acid, 4-(aminomethyl)-, trans- TRANEXAMIC ACID	(CAS-No.) 1197-18-8	1.0	Not classified.
Sodium chloride	Sodium salt of hydrochloric acid Salt SEA SALT SODIUM CHLORIDE Sodium chloride (NaCl) Sea salt	(CAS-No.) 7647-14-5	0.7	Not classified.

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\*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%). Full text of H-statements: see section 16.

### SECTION 4: FIRST AID MEASURES

#### 4.1. Description of First-aid Measures

**General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

**Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**Skin Contact:** Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

**Eye Contact:** Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

**Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

#### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**General:** Not expected to present a significant hazard under anticipated conditions of normal use.

**Inhalation:** Prolonged exposure may cause irritation.

**Skin Contact:** Prolonged exposure may cause skin irritation.

**Eye Contact:** May cause slight irritation to eyes.

**Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

#### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

### SECTION 5: FIRE-FIGHTING MEASURES

#### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Solutions do not burn. Use extinguishing media appropriate for surrounding fire.

**Unsuitable Extinguishing Media:**

#### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Product is not flammable.

**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

#### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Sodium oxides.

**Other Information:** No additional information available.

#### 5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

##### 6.1.1. For Non-Emergency Personnel

**Protective Equipment:** Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

##### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

#### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

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### 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Material may be biologically contaminated with pathogenic organisms during use.

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with EC Directive 2010/32/EU.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

**Incompatible Materials:** Strong acids, strong bases, strong oxidizers.

**Storage Temperature:** Store at 20 – 25°C (68 – 77°F). Temporary excursions permitted to 15°C – 30 °C (59°F – 86 °F).

### 7.3. Specific End Use(s)

Tranexamic Acid in Sodium Chloride Injection is indicated in patients with hemophilia for short-term use (two to eight days) to reduce or prevent hemorrhage and reduce the need for replacement therapy during and following tooth extraction.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

### 8.2. Exposure Controls

**Appropriate Engineering Controls:** Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

**Personal Protective Equipment:** Gloves. Protective clothing. Protective goggles or glasses.



**Materials for Protective Clothing:** Chemically resistant materials and fabrics.

**Hand Protection:** Wear protective gloves.

**Eye and Face Protection:** Chemical goggles or safety glasses.

**Skin and Body Protection:** Wear suitable protective clothing.

**Respiratory Protection:** If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

**Thermal Hazard Protection:** Not applicable.

**Environmental Exposure Controls:** Avoid unnecessary release into the environment.

**Other Information:** When using, do not eat, drink or smoke.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

**Physical State** : Liquid

**Appearance** : Colorless solution

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<b>Odor</b>	: No data available
<b>Odor Threshold</b>	: No data available
<b>pH</b>	: 6.5 – 8.0
<b>Evaporation Rate</b>	: No data available
<b>Melting Point</b>	: No data available
<b>Freezing Point</b>	: No data available
<b>Boiling Point</b>	: No data available
<b>Flash Point</b>	: No data available
<b>Auto-ignition Temperature</b>	: No data available
<b>Decomposition Temperature</b>	: No data available
<b>Flammability (solid, gas)</b>	: Not applicable
<b>Lower Flammable Limit</b>	: No data available
<b>Upper Flammable Limit</b>	: No data available
<b>Vapor Pressure</b>	: No data available
<b>Relative Vapor Density at 20°C</b>	: No data available
<b>Relative Density</b>	: No data available
<b>Specific Gravity</b>	: No data available
<b>Solubility</b>	: Water: Miscible
<b>Partition Coefficient: N-Octanol/Water</b>	: No data available
<b>Viscosity</b>	: No data available

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

### 10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

### 10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

### 10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

### 10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

### 10.6. Hazardous Decomposition Products:

Not expected to decompose under ambient conditions.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects - Product

**Likely routes of exposure:** Dermal, Eye Contact, Inhalation, Oral.

**Acute Toxicity (Oral):** Not classified.

**Acute Toxicity (Dermal):** Not classified.

**Acute Toxicity (Inhalation):** Not classified.

#### LD50 and LC50 Data:

No additional information available

**Skin Corrosion/Irritation:** Not classified.

**pH:** 6.5 – 8.0

**Eye Damage/Irritation:** Not classified.

**pH:** 6.5 – 8.0

**Respiratory or Skin Sensitization:** Not classified.

**Germ Cell Mutagenicity:** Not classified.

**Carcinogenicity:** Not classified.

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified.

**Reproductive Toxicity:** Not classified.

**Specific Target Organ Toxicity (Single Exposure):** Not classified.

**Aspiration Hazard:** Not classified.

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

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**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

### 11.2. Information on Toxicological Effects - Ingredient(s)

#### LD50 and LC50 Data:

<b>Sodium chloride (7647-14-5)</b>	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 mg/l (Exposure time: 1 h Source: ECHA_API)
<b>Water (7732-18-5)</b>	
LD50 Oral Rat	> 90 ml/kg (Source: FOOD_JOURN)

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General:** Not classified.

<b>Sodium chloride (7647-14-5)</b>	
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static] Source: EPA)
EC50 - Crustacea [2]	340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)

### 12.2. Persistence and Degradability

<b>Tranexamic Acid in Sodium Chloride Injection</b>	
Persistence and Degradability	Expected to be biodegradable.

### 12.3. Bioaccumulative Potential

<b>Tranexamic Acid in Sodium Chloride Injection</b>	
Bioaccumulative Potential	Not expected to bioaccumulate.
<b>Sodium chloride (7647-14-5)</b>	
BCF Fish 1	(no bioaccumulation)

### 12.4. Mobility in Soil

<b>Tranexamic Acid in Sodium Chloride Injection</b>	
Ecology - Soil	Adsorbs into the soil. Leaches into groundwater.

### 12.5. Other Adverse Effects

**Other Adverse Effects:** None known.

**Other Information:** Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

**Waste Treatment Methods:** Can be landfilled or incinerated, when in compliance with local regulations.

**Sewage Disposal Recommendations:** Do not dispose of waste into sewer. Do not empty into drains.

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

**Additional Information:** Biologically contaminated materials should be incinerated.

**Ecology - Waste Materials:** Avoid unnecessary release into the environment.

## SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

### 14.1. In Accordance with DOT

Not regulated for transport

### 14.2. In Accordance with IMDG

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Not regulated for transport

### 14.3. In Accordance with IATA

Not regulated for transport

### 14.4. In Accordance with TDG

Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1. US Federal Regulations

#### Sodium chloride (7647-14-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

#### Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

### 15.2. US State Regulations

Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed.

### 15.3. Canadian Regulations

#### Sodium chloride (7647-14-5)

Listed on the Canadian DSL (Domestic Substances List)

#### Water (7732-18-5)

Listed on the Canadian DSL (Domestic Substances List)

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

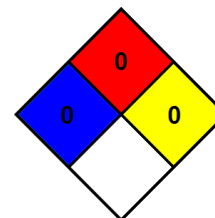
Date of Preparation or Latest Revision : 12/05/2024

### Revision

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

### GHS Full Text Phrases:

- NFPA Health Hazard** : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.
- NFPA Fire Hazard** : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.
- NFPA Reactivity Hazard** : 0 - Material that in themselves are normally stable, even under fire conditions.



### HMIS III Rating

- Health** : 0 Minimal Hazard - No significant risk to health
- Flammability** : 0 Minimal Hazard
- Physical** : 0 Minimal Hazard
- Personal protection** : B

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### Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)

AU\_WES: Australia WES

CHEMVIEW: ChemView (U.S. Environmental Protection Agency)

EC\_RAR: European Commission Renewal Assessment Report

EC\_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits

ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports

ECHA\_API: European Chemicals Agency API

ECHA\_RAC: ECHA Committee for Risk Assessment

EFSA: European Food Safety Authority

EPA: U.S. Environmental Protection Agency

EPA\_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)

12/05/2024

FOOD\_JOURN: Food Research Journal (1956)

IARC: The International Agency for Research on Cancer

IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles

IUCLID: International Uniform Chemical Information Database

JAPAN\_GHS: Japan GHS Basis for Classification Data

JP\_J-CHECK: Japan J-Check

KR\_NIER: South Korea National Institute of Environmental Research Evaluations

NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme

NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)

NLM\_CIP: National Library of Medicine ChemID plus database

NLM\_HSDB: National Library of Medicine Hazardous Substance Data Bank

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Agency)

EPA\_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)

EPA\_HPVC: High Production Volume Chemicals (U.S. Environmental Protection Agency)

EPA\_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)

EU\_CLH: European Union Harmonised Classification and Labelling Proposal

EU\_RAR: European Union Risk Assessment Report

NLM\_PUBMED: National Library of Medicine PubMed database

NTP: National Toxicology Program

NZ\_CCID: New Zealand Chemical Classification and Information Database

OECD\_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)

OECD\_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)

WHO: World Health Organization

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*

NA GHS SDS 2015 (Can, US)