

Section 1: Identification of the Substance/Mixture and of the Company Undertaking

Product identifier used on the label:

Product Name: Tranexamic Acid Injection, 100 mg/mL

Other means of identification:

Recommended use of the chemical and restrictions on use:

Chemical manufacturer address and telephone number:

Manufacturer Name: Fresenius Kabi USA, LLC

Manufacturer Address 1: Three Corporate Drive

Manufacturer City: Lake Zurich

Manufacturer State: Illinois

Manufacturer Zip Code: 60047

Business Phone: (847) 550-2300

Customer Service Phone: (888) 386-1300

Health Phone: (800) 551-7176

Emergency phone number:

Revision Date: 06/01/2015

Section 2: Hazards Identification

Classification of the chemical in accordance with CFR 1910.1200(d)(f):

Signal Words: Not applicable.

Hazard Statements: Not applicable.

Precautionary Statements: Not applicable.

Hazards not otherwise classified that have been identified during the classification process:

Section 3: Composition/Information on Ingredients

Mixtures:

Ingredient Name	CAS Number	Ingredient Percent	EC Number	Comments
Tranexamic acid	1197-18-8	100 mg/ml		
Water for Injection	7732-18-5	Quantity Sufficient		

Section 4: First Aid Measures

Description of necessary measures:

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and delayed:

Other First Aid: For Adverse Event Information, please call (800) 551-7176.

Indication of immediate medical attention and special treatment needed

Note To Physicians:

An antagonist (such as neostigmine, edrophonium) in conjunction with an appropriate anticholinergic agent can be given once evidence of recovery from the neuromuscular block is observed.

Section 5: Firefighting Measures

Suitable and unsuitable extinguishing media**Extinguishing Media:**

Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards arising from the chemical**Hazardous Combustion Byproducts:**

Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

Special protective equipment and precautions for fire-fighters**Fire Fighting Instructions:**

Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

Protective Equipment:

As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures**Personnel Precautions:**

Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.

Methods and materials for containment and cleaning up**Methods for Containment:**

Contain spills with an inert absorbent material such as soil, sand or oil dry.

Methods for Cleanup:

Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

Environmental precautions**Environmental Precautions:**

Avoid runoff into storm sewers, ditches, and waterways.

Section 7: Handling and Storage

Precautions for safe handling**Handling:**

When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.

Work Practices:

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Hygiene Practices:

Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

Conditions for safe storage, including any incompatibilities**Storage:**

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

Exposure Guidelines**Exposure Guidelines - Ingredient Based:**

Tranexamic acid:

ACGIH: Not established.

OSHA: Not established.

Appropriate engineering controls

Engineering Controls: General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

Individual protection measures

Eye Protection: Chemical splash goggles. Wear a face shield also when splash hazard exist.

Skin Protection: Protective laboratory coat, apron, or disposable garment recommended.

Hand Protection: Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.

Respiratory Protection: No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (<http://www.cdc.gov/niosh/nppt/topics/respirators/>) for a list of respirator types and approved suppliers.

Other Protective: Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

Hygiene Practices: Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

Section 9: Physical and Chemical Properties**Physical and chemical properties**

Physical State:	Liquid.
Color:	Colorless.
pH:	6.5 - 8.0
Melting Temperature:	Not established.
Boiling Temperature:	Not established.
Flash Point:	Not established.
Flash Point Method:	Not established.
Ignition Temperature:	Not established.
Lower Flammable Limit:	Not established.
Upper Flammable Limit:	Not established.
Vapor Pressure:	Not established.
Vapor Density:	Not established.
Solubility:	No Data
Percent Volatile:	Not established.
Molecular Formula:	Mixture

Section 10: Stability and Reactivity**Reactivity:****Chemical Stability:**

Chemical Stability: Stable under normal temperatures and pressures.

Possibility of hazardous reactions:

Hazardous Polymerization: Not reported.

Conditions To Avoid:

Conditions To Avoid: No conditions contributing to instability are known to exist for normal handling of this product.

Incompatible Materials:**Section 11: Toxicological Information****Toxicological Information:****Tranexamic acid:****Ingestion Toxicity:**

Oral - Mouse LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value]
Oral - LD50: >5 gm/kg [Details of toxic effects not reported other than lethal dose value]
Oral - LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value]

Chronic Eye Toxicity:

Intravenous. - Rat LD50: 1200 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Mouse LD50: 1350 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - LD50: 1110 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 4200 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse LD50: 5310 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse LD50: 5310 mg/kg [Details of toxic effects not reported other than lethal dose value]

Potential Health Effects:

Contraindications: In patients with acquired defective color vision, subarachnoid hemorrhage, active intravascular clotting, or hypersensitivity to tranexamic acid or any of the ingredients.
Precautions: Tranexamic acid, when given from 6 days to 1 year, has been shown to cause local areas of retinal degeneration in cats, dogs, and rats following oral or intravenous administration at doses between 6 to 40 times the recommended human dose. Convulsions have been reported in association with tranexamic acid treatment.

Adverse Reactions: Gastrointestinal disturbances, allergic dermatitis, giddiness, hypotension, convulsion, chromatopsia, thromboembolic events, and visual impairment have been reported.

Route of Exposure:

Inhalation, Ingestion, Eye contact, Skin Absorption., Injection.

Sign and Symptoms:

Symptoms of overdose may include nausea, vomiting, diarrhea, hypotension, thromboembolic effects, visual impairment, convulsions, mental status changes, myoclonus or rash.

Acute Inhalation Effects:

May cause irritation of respiratory tract.

Acute Skin Effects:

May cause skin irritation.

Acute Ingestion Effects:

May cause irritation.

Acute Eye Effects:

Contact with eyes may cause irritation.

Tranexamic acid:**Mutagenicity:**

Tranexamic acid was negative for mutagenicity in several in vivo and in vitro tests.

Reproductive Toxicity:

Reproduction studies involving mice, rats, and rabbits did not reveal adverse effects in the offspring or evidence of impaired fertility related to tranexamic acid.

Section 12: Ecological Information

Ecotoxicity:

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

Persistence and degradability:**Bioaccumulative potential:****Mobility in soil:****Section 13: Disposal Considerations****Description of waste:**

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

Section 14: Transport Information

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated.

Section 15: Regulatory Information**Safety, health and environmental regulations specific for the product:****Regulatory - Product Based:****Canada WHMIS:**

Controlled - Class: D2B Toxic

Canada Reg. Status:

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all of the information required by the Controlled Products Regulations.

Regulatory - Ingredient Based:**Tranexamic acid:**

TSCA Inventory Status: Listed

EC Number: 214-818-2

Section 16: Additional Information

Issue Date: 02/01/2012

Revision Date: 06/01/2015

Disclaimer: The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

HMIS:

Health	1
Flammability	1
Reactivity	1
PPE	X

Chronic Health Hazard

Other Information:

