

# Tranexamic Acid Injection, 100 mg/mL

## Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations  
Revision Date: 08/04/2015 Date of issue: 08/04/2015

Version: 1.0

### SECTION 1: IDENTIFICATION

#### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Tranexamic Acid Injection, 100 mg/mL

**Product Code:** (NDC) 100 mg/mL: 0517-0960-01, 0517-0960-10

#### 1.2. Intended Use of the Product

**Use of the substance/mixture:** Pharmaceutical product used as blood clotting agent.

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

##### Company

PharmaForce, Inc.  
6610 New Albany Road East  
New Albany, OH 43054  
T 614-436-2222

[www.pharmaforceinc.com](http://www.pharmaforceinc.com)

##### Distributor

American Regent, Inc.  
One Luitpold Drive  
P.O. Box 9001  
Shirley, NY 11967

1-800-645-1706

[www.luitpold.com](http://www.luitpold.com)

#### 1.4. Emergency Telephone Number

**Emergency Number** : 1-800-424-9300 CHEMTREC

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1. Classification of the Substance or Mixture

##### Classification (GHS-US)

Skin Irrit. 2 H315

Eye Irrit. 2A H319

Full text of H-phrases: see section 16

#### 2.2. Label Elements

##### GHS-US Labeling

##### Hazard Pictograms (GHS-US)



GHS07

##### Signal Word (GHS-US)

: Warning

##### Hazard Statements (GHS-US)

: H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

##### Precautionary Statements (GHS-US)

: P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.

P280 - Wear protective gloves, protective clothing, and eye protection.

P302+P352 - If on skin: Wash with plenty of water.

P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P321 - Specific treatment (see section 4 on this SDS).

P332+P313 - If skin irritation occurs: Get medical advice/attention.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P362 - Take off contaminated clothing and wash it before reuse.

**2.3. Other Hazards** Common adverse effects are retinal changes and degeneration and visual disturbances. Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions.

**2.4. Unknown Acute Toxicity (GHS-US)** No data available

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**3.1. Substance** Not applicable

#### 3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Water for injection	(CAS No) 7732-18-5	90	Not classified
Tranexamic acid	(CAS No) 1197-18-8	10	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335

Full text of H-phrases: see section 16

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## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First Aid Measures

**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). In the event of accidental injection, immediately call a poison center or seek medical advice.

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

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Eye Contact:** Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

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

**Symptoms/Injuries:** Causes irritation.

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

**Symptoms/Injuries After Skin Contact:** Redness, pain, swelling, itching, burning, dryness, and dermatitis.

**Symptoms/Injuries After Eye Contact:** Contact causes severe irritation with redness and swelling of the conjunctiva.

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

**Chronic Symptoms:** None known.

### 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:** Use extinguishing media appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

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

**Fire Hazard:** Not considered flammable but may burn at high temperatures.

**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.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

**General Measures:** Avoid breathing (vapor, mist, spray). Avoid all contact with skin, eyes, or clothing.

#### 6.1.1. For Non-emergency Personnel

**Protective Equipment:** Use appropriate personal protection equipment (PPE) as recommended in Section 8.

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Responders

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

**Emergency Procedures:** 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.

### 6.3. Methods and Material 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, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Use only as directed by the information identified in the package insert.

**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 breathing vapors, mist, spray. Avoid contact with skin, eyes and clothing.

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

**Incompatible Products:** Strong oxidizers.

**7.3. Specific End Use(s)** Pharmaceutical product used as blood clotting agent.

## 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), NIOSH (REL), or OSHA (PEL).

### 8.2. Exposure Controls

**Appropriate Engineering Controls** : Emergency eye wash fountains and safety showers should be available in the immediate 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.



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

**Hand Protection** : Wear protective gloves.

**Eye Protection** : Chemical safety goggles.

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

**Respiratory Protection** : In case of inadequate ventilation wear respiratory protection.

**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

<b>Physical State</b>	: Liquid
<b>Appearance</b>	: Clear, Colorless
<b>Odor</b>	: Mild
<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>	: $\approx 100\text{ }^{\circ}\text{C}$ ( $212\text{ }^{\circ}\text{F}$ )
<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>	: 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>	: Approximate to water
<b>Solubility</b>	: Soluble in water
<b>Partition Coefficient: N-Octanol/Water</b>	: No data available
<b>Viscosity</b>	: No data available

**9.2. Other Information** No additional information 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 oxidizers.

**10.6. Hazardous Decomposition Products:** Nitrogen oxides.

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## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information On Toxicological Effects

**Acute Toxicity:** Not classified

**Skin Corrosion/Irritation:** Causes skin irritation. (pH: 6.5 - 8.0)

**Serious Eye Damage/Irritation:** Causes serious eye irritation. (pH: 6.5 - 8.0)

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

**Reproductive Toxicity:** Not classified

US FDA Pharmaceutical Pregnancy Category B: Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester.

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

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

**Aspiration Hazard:** Not classified

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

**Symptoms/Injuries After Skin Contact:** Redness, pain, swelling, itching, burning, dryness, and dermatitis.

**Symptoms/Injuries After Eye Contact:** Contact causes severe irritation with redness and swelling of the conjunctiva.

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

**Chronic Symptoms:** None known.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General** : Not classified.

**12.2. Persistence and Degradability** Not established

**12.3. Bioaccumulative Potential** Not established

**12.4. Mobility in Soil** No additional information available

**12.5. Other Adverse Effects**

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

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

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

**Additional Information:** Container may remain hazardous when empty. Continue to observe all precautions.

**Ecology – Waste Materials:** Avoid release to the environment.

## SECTION 14: TRANSPORT INFORMATION

**14.1. In Accordance with DOT** Not regulated for transport

**14.2. In Accordance with IMDG** Not regulated for transport

**14.3. In Accordance with IATA** Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1 US Federal Regulations

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SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard Delayed (chronic) health hazard

### Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

**15.2 US State Regulations** Neither this product nor its chemical components appear on any US state lists.

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

**Revision Date** : 08/04/2015

**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

### GHS Full Text Phrases:

Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3

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H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation

Refer to Luitpold/American Regent prescribing information for further information at: <http://americanregent.com/AllProducts.aspx>

*The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.*

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