

 <b>Pharmaceutical Division</b>	<b>Tranexamic Acid Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>07JUN2017</b>	SDS No.: <b>SDS009</b>	Revision No: <b>01</b>	Page <b>1 of 8</b>

### Section 1 - Identification

**(a) Product Identifier:** Tranexamic Acid Injection  
**(b) Product Code:** 70860-400  
**Common/Trade Name:** Cyklokapron  
**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:** Athenex Pharmaceutical Division, 10 N. Martingale Road,  
Suite 230, Schaumburg, IL 60173, 847-886-9515  
**(e) Emergency Telephone:** 855-273-0154

### Section 2 - Hazards Identification

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

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

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

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### Section 3 – Composition / Information on Ingredients

<b>(a) Chemical Name</b>	<b>(b) Common Name / Synonym</b>	<b>% Composition or other measure</b>	<b>(c) CAS No.</b>	<b>(d) Impurities / Stabilizing Additives</b>
trans -4-(Aminomethyl) cyclohexanecarboxylic acid	Tranexamic Acid	10	1197-18-8	N/A*

\*The formula also contains water for injection that has a pH of 6.5 to 8.0.

### Section 4 – First Aid Measures

<b>Eye Exposure:</b>	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Skin Exposure:</b>	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Ingestion:</b>	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
<b>Injection:</b>	In cases of accidental injection, wash and disinfect area, seek medical attention.
<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Notes to physician</b>	Treat symptomatically. See patient package insert in shipping carton for complete information.

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## Section 5 – Fire-fighting Measures

- (a) Extinguishing Media** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.
- (b) Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- (c) Special Protective Equipment / Precautions:** Wear self-contained breathing apparatus and full and protective gear.

## Section 6 - Accidental Release Measures

**Spill:** Pick up in the most efficient manner. Collect spill with absorbent material. Clean spill area thoroughly. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

**Release to Air:** Not available.

**Release to Water:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

## Section 7 - Handling and Storage

**General Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

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

## Section 8 - Exposure Controls / Personal Protection

### (a) Exposure Limits

<b>Compound</b>	<b>Issuer</b>	<b>Type</b>	<b>Exposure Limit</b>
Tranexamic Acid	OSHA ACGIH -----	TLV PEL STEL	NE NE NE

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## (b) Engineering Controls

Engineering controls should be used as the primary means to control exposures.

## (c) Individual Protection Measures

Respiratory Protection:	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Eye Protection:	Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin Protection:	Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
Other Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Additional Exposure Precautions:	None available

## Section 9 - Physical and Chemical Properties

<b>(a)</b>	<b>Appearance</b>	Colorless liquid
<b>(b)</b>	<b>Odor</b>	Not available
<b>(c)</b>	<b>Odor Threshold</b>	Not available
<b>(d)</b>	<b>pH</b>	6.5-8.0
<b>(e)</b>	<b>Melting Point:</b>	Not available
<b>(f)</b>	<b>Initial Boiling Point:</b>	Not available
<b>(g)</b>	<b>Flash Point</b>	Not available
<b>(h)</b>	<b>Evaporation Rate:</b>	Not available
<b>(i)</b>	<b>Flammability</b>	Not available
<b>(j)</b>	<b>Upper Lower Flammability or Explosion Limits</b>	Not available
<b>(k)</b>	<b>Vapor Pressure:</b>	Not available
<b>(l)</b>	<b>Vapor Density:</b>	Not available

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<b>(m)</b>	<b>Relative Density</b>	Not available
<b>(n)</b>	<b>Solubility(ies)</b>	Not applicable
<b>(o)</b>	<b>Partition Coefficient: n-octanol/water</b>	Not available
<b>(p)</b>	<b>Auto-ignition Temperature</b>	Not available
<b>(q)</b>	<b>Decomposition Temperature</b>	Not available
<b>(r)</b>	<b>Viscosity</b>	Not available

### Section 10 - Stability and Reactivity

<b>(a)</b>	<b>Reactivity</b>	No specific test data related to reactivity available for this product or its ingredients.
<b>(b)</b>	<b>Chemical Stability</b>	The product is stable under normal conditions of use.
<b>(c)</b>	<b>Possibility of Hazardous Reactions</b>	None known.
<b>(d)</b>	<b>Conditions to Avoid</b>	Heat and light
<b>(e)</b>	<b>Incompatible Materials</b>	As a precautionary measure, keep away from strong oxidizers.
<b>(f)</b>	<b>Hazardous Decomposition Products</b>	None known.

### Section 11 - Toxicological Information

<b>(a)</b>	<b>Likely Routes of Exposure</b>	Not available.
<b>(b)</b>	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	May cause skin and eye irritation.
<b>(c)</b>	<b>Delayed and immediate effects and also chronic effects from short and long term exposure</b>	None available.

### (d) Acute Toxicity

Component	Type	Route	Species	Dosage
Tranexamic Acid	LD <sub>50</sub>	Oral	Rat	>10,000 mg/kg
	LD <sub>50</sub>	Oral	Mouse	>10,000 mg/kg
	LD <sub>50</sub>	Intravenous	Rat	1,330 mg/kg
	LD <sub>50</sub>	Intravenous	Mouse	1,350 mg/kg
	LD <sub>50</sub>	Subcutaneous	Rat	4,620 mg/kg

### (e) Hazardous Chemical Listings

NTP: Not Listed

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IARC: Not Listed

OSHA: Not Listed

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### Section 12 - Ecological Information

<b>(a)</b>	<b>Ecotoxicity</b>	The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.
<b>(b)</b>	<b>Persistence and degradability</b>	Not Available
<b>(c)</b>	<b>Bioaccumulative potential</b>	Not Available
<b>(d)</b>	<b>Mobility in soil</b>	Not Available
<b>(e)</b>	<b>Other Adverse Effects</b>	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.

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

### Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division 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: Not listed

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 304: Not regulated

SARA 313 - Not on this list

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## **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:

Athenex Pharmaceutical Division  
10 N. Martingale Road, Suite 230  
Schaumburg, IL 60173  
847-886-9515

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this 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

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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

## Signature Manifest

**Document Number:** SDS009  
**Title:** Tranexamic Acid Injection

**Revision:** 01

All dates and times are in Eastern Standard Time.

**SDS009**

### Change Request

Name/Signature	Title	Date	Meaning/Reason
Michael Scribner (MSCRIBNER)	Director of Quality	05 Jun 2017, 05:32:53 PM	Approved

### Dept Approval

Name/Signature	Title	Date	Meaning/Reason
Tom Moutvic (TMOUTVIC)	VP of Regulatory Affairs	06 Jun 2017, 10:39:32 AM	Approved

### Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	06 Jun 2017, 11:06:01 AM	Approved