Section 1 - Identification

(a)	**Product Identifier:**	Tranexamic Acid Injection, USP
(b)	**NDC:**	25021-415-10, 25021-415-66
	Common/Trade Name:	Cyklokapron®
	Chemical Name:	Trans -4-(Aminomethyl)cyclohexanecarboxylic acid
	Chemical Family:	Derivative of the amino acid lysine
(c)	**Product Use:**	Antifibrinolytic agent
	Product Type:	Regulated Prescription Drug
	Container Information:	Vials
(d)	**Distributor:**	Sagent Pharmaceuticals, 1515 E Woodfield Road Suite 1100, Schaumburg, IL 60173, 847-908-1600
(e)	**Emergency Telephone:**	866-625-1618

Section 2 - Hazards Identification

(a)	**Classification:**	**NFPA Rating** Health Hazard**:** N/A Fire Hazard**:** N/A Reactivity Hazard**:** N/A
(b)	**Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):**	Warning.
(c)	**Description of Hazards:**	N/A
(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, USP	100 mg/mL	1197-18-8	N/A
Water	Water for Injection	q.s to 1 mL	7732-18-5	N/A

Section 4 - First Aid Measures

Eye Exposure: 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.

Skin Exposure: 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.

Ingestion: 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.

Inhalation: 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.

Notes to Physician: See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures

(a) Extinguishing Media Extinguish fires with CO2, 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: 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: N/A

Release to Environment: 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: Gloves, masks and goggles are recommended during handling.

Storage Conditions: Store at 20º to 25°C (68º to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Tranexamic Acid	OEL	TWA	1500µg/m^3

(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:	N/A
Additional Exposure Precautions:	N/A

Section 9 - Physical and Chemical Properties

(a)	**Appearance**	Clear, colorless solution
(b)	**Odor**	N/A
(c)	**Odor Threshold**	N/A
(d)	**pH**	6.5 – 8.0
(e)	**Melting Point:**	N/A
(f)	**Initial Boiling Point:**	N/A
(g)	**Flash Point**	N/A
(h)	**Evaporation Rate:**	N/A
(i)	**Flammability**	N/A
(j)	**Upper Lower Flammability or Explosion Limits**	N/A
(k)	**Vapor Pressure:**	N/A
(l)	**Vapor Density:**	N/A
(m)	**Relative Density**	N/A
(n)	**Solubility(ies)**	Soluble in water.
(o)	**Partition Coefficient: n-octanol/water**	N/A

(p)	**Auto-ignition Temperature**	N/A
(q)	**Decomposition Temperature**	N/A
(r)	**Viscosity**	N/A

Section 10 - Stability and Reactivity

(a)	**Reactivity**	N/A
(b)	**Chemical Stability**	Stable under normal use and storage conditions.
(c)	**Possibility of Hazardous Reactions**	N/A
(d)	**Conditions to Avoid**	Strong oxidizers.
(e)	**Incompatible Materials**	As a precautionary measure, keep away from strong oxidizers.
(f)	**Hazardous Decomposition Products**	N/A

Section 11 - Toxicological Information

(a)	**Likely Routes of Exposure**	Ingestion, Inhalation, skin, eye
(b)	**Symptoms related to the physical, chemical and toxicological characteristics**	Prolonged exposure may cause irritation. Redness, pain, swelling, itching, burning, dryness, and dermatitis. Contact causes severe irritation with redness and swelling of the conjunctiva.
(c)	**Delayed and immediate effects and also chronic effects from short and long term exposure**	N/A

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Tranexamic Acid	LD_{50}	Intravenous	Rat	>1330 mg/kg
	LD_{50}	Inhalation	Mouse	>1350 mg/kg
	LD_{50}	Subcutaneous	Rat	>4620 mg/kg

(e) Hazardous Chemical Listings

NTP: No **IARC**: No **OSHA**: No **NIOSH**: No

(f) Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Tranexamic acid was not carcinogenic in a 2-year study in rats and mice at oral doses up to 3 and 5.3 g/kg/day, which are approximately 12 and 11 times the maximum recommended human dose based on body surface area, respectively.

Mutagenesis: Tranexamic acid was not genotoxic in the reverse mutation bacterial (Ames) test, and *in vitro* and *in vivo* cytogenetic test.

Impairment of Fertility: In a fertility and early embryonic development study, tranexamic acid was administered to male rats as 0.3% and 1% of drug in diet (average doses of 222 and 856 mg/kg/day) or to female rats at dose levels of 0.3% and 1.2% of drug in diet. Tranexamic acid had no effect on fertility or reproductive function of male or female rats at dose multiples of 4 or 5 times the maximum recommended human dose based on body surface area, respectively.

Section 12 - Ecological Information

(a)	**Ecotoxicity**	N/A
(b)	**Persistence and degradability**	N/A
(c)	**Bioaccumulative potential**	N/A
(d)	**Mobility in soil**	N/A
(e)	**Other Adverse Effects**	N/A

Section 13 - Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

Section 14 - Transport Information

(a)	**UN Number**	N/A
(b)	**UN Proper Shipping Name**	N/A
(c)	**Transport Hazard Class(es)**	N/A
(d)	**Packing Group**	N/A
(e)	**Environmental Hazards**	N/A
(f)	**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)**	N/A
(g)	**Special Precautions**	N/A

DOT: Not dangerous goods.

IATA: Not dangerous goods.
IMDG: Not dangerous goods.

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent use. 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 on this list
CERCLA: Not on this list
SARA 302: Not on this list
SARA 313: Not on this list
CA Prop 65: Not on this list
RCRA: Not on this list

Section 16 - Other Information

As of the date of issuance, 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:
Sagent Pharmaceuticals
1515 E Woodfield Road Suite 1100, Schaumburg, IL 60173
847-908-1600

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
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)

IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
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
NIOSH	National Institute for Occupational Safety and Health
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)