

ACIDUM TRANEXAMICUM

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	EN: Tranexamic acid
	LAT: Acidum tranexamicum
	NL: Tranexaminezuur
	FR: Tranexamique (acide)
	DE: Tranexamsäure
N° CAS:	1197-18-8
N° EC:	214-818-2

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Skin irritation (category 2)	H315
Eye irritation (category 2)	H319
STOT SE(category 3)	H335

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	
Signal word(s):	Attention
Hazard statements:	

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H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P264	Wash hands [and ...] thoroughly after handling.
P264+P265	Wash hands [and ...] thoroughly after handling. Do not touch eyes.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P302+P352	IF ON SKIN: wash with plenty of water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
P319	Get medical help if you feel unwell.
P321	Specific treatment (see on this label).
P332+P317	If skin irritation occurs: Get medical help.
P337+P317	If eye irritation persists: Get medical help.
P362+P364	Take off contaminated clothing and wash it before reuse.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Other hazards not contributing to the classification : Exposure may produce an allergic reaction.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Tranexamic acid
IUPAC name:	4-(aminomethyl)cyclohexane-1-carboxylic acid
Synonyms:	Lysteda Tranexamsaeure Cyclocapron Femstrual
N° CAS:	1197-18-8
N° EC:	214-818-2
Molecular Formula:	C ₈ H ₁₅ NO ₂



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Content: 99.0 % to 101.0 % (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Not applicable.

After inhalation: Move to fresh air in case of accidental inhalation. Assure fresh air breathing.

After skin contact: Rinse skin with water/shower.

After eye contact: Rinse with water while holding the eyes wide open. Contact lenses should be removed.

After ingestion: Rinse mouth out with water.

Self-protection of the first aider: Not applicable.

4.2 Most important symptoms and effects, both acute and delayed

See section 2.

4.3 Indication of any immediate medical attention and special treatment needed

In all cases of doubt or when symptoms persist, seek medical attention.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Small amounts : use extinguishing media appropriate for surrounding fire. Water spray. Carbon dioxide. Dry powder. Foam.
Large amounts: Not applicable.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires: Dilute with water.

Protection against fire: Small amounts. Use normal individual fire protective equipment.
Large amounts: Not Applicable.

Hazardous combustion products: Not available.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

General measures

Avoid raising dust, wear suitable protective clothing, gloves and eye or face protection.

For non-emergency personnel

Protective equipment: See Section 7 and 8.

For emergency responders

Not available.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Sweep spilled substances into containers, if appropriate, moisten first to prevent dusting. Waste is collected and contained. Clean thoroughly. Clean with water.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Additional hazards when processed: When used and handled according to specifications, the product does not have any harmful effects according to our experiences and the information provided to us. Handle in accordance with good industrial hygiene and safety procedures.
Personal protection:	See section 8.
Technical protective measures:	Comply with applicable regulations.
Handling:	Handle and open container with care.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Container.
Conditions for safe storage, including any incompatibilities:	To guarantee the quality and properties of the product, keep container tightly closed in a dry and well-ventilated place away from heat. Store at below 30°C.
Storage – away from:	Keep away from heat.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection: Safety glasses.

Skin protection: Lab coat.

Hand protection: Gloves.

Respiratory protection: For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator.

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Solid. White crystals or crystalline powder.

Odour: Not available.

Odour threshold: Not available.

pH: 7-8

Melting/freezing point: 386-390 °C

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

Vapour density: Not available.

Relative density: Not available.

Solubility: Freely soluble in water and in glacial acetic acid, practically insoluble in acetone and in ethanol (96 %).

Solubility in water: Freely soluble in water.

Partition coefficient: -1.9 at 20 °C.



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(n-octanol/water):

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal condition.

10.2 Chemical stability

Not available.

10.3 Possibility of hazardous reactions

Small amounts : when used and handled according to specification, the product does not have any harmful effects according to our experiences and the information provided to us.

Large amounts: Not applicable.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Small amounts : None under normal use.

Large amounts: Not applicable.

10.6 Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

Large amounts : Not applicable.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not available.

LD₅₀ oral rat: > 10000 mg/kg

Skin corrosion/irritation: Cause skin irritation, pH 7-8

Serious eye damage/irritation: Causes serious eye irritation, pH 7-8

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: Not available.

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Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	May cause reparatory irritation.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	<p>Potential adverse human health effects and symptoms : Avoid any direct contact with the product.</p> <p>Small amounts: when used and handled according to specifications, the product dose not has any harmful effects according to our experiences and the information provided to us.</p> <p>Large amounts : Not applicable.</p>

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecology – general : Small amounts : See Section 2. Large amounts : Not applicable.
Ecology – water : Soluble in water.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Tranexamic acid [1197-18-8]: Log Pow: -1.9 at 20°C.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Regional legislation (waste): Dispose in a safe manner in accordance with local/national regulations.



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SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : No dangerous good in sense of transport regulations.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

Safety phrases: Not applicable.

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

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16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS



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