

Tranexamic acid

Safety Data Sheet

648132

Version: 3.1

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU)

2015/830

Issue date: 19/10/2011 Revision date 08/01/2021

Supersedes 21/11/2018

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	: Substance
Substance name	: Tranexamic acid
IUPAC name	: trans-4-Aminomethylcyclohexanecarboxylic acid
CAS-No.	: 1197-18-8
Product code	: 648132
Formula	: C ₈ H ₁₅ NO ₂
Product group	: Raw material

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category	: Pharmaceutical industry
Industrial/Professional use spec	: For professional use only
Use of the substance/mixture	: Active ingredient for the preparation of pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
 A. Hofmanweg 71
 2031BH Haarlem - Nederland
 T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number	: Supplier contact information: +31(0)23-5319093 (M-F 09:00-17:00) +31(0)6-30109355 (outside office hours)
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Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] show CLP information only

Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319

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Specific target organ toxicity — Single exposure, Category 3, H335
Respiratory tract irritation

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display
classification(s) to display

Hazard pictograms (CLP)

:



GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.

Precautionary statements (CLP)

: P261 - Avoid breathing dust.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312 - Call a POISON CENTER/doctor if you feel unwell.
P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Tranexamic acid	(CAS-No.) 1197-18-8	99 - 101	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: If possible show this sheet, if not available show packaging or label.
First-aid measures after inhalation	: Allow affected person to breathe fresh air Obtain medical attention if breathing difficulty persists.
First-aid measures after skin contact	: Wash skin with mild soap and water Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Rinse immediately with plenty of water If eye irritation persists, take medical advice.
First-aid measures after ingestion	: Rinse mouth. Seek medical attention immediately Never give anything by mouth to an unconscious person.

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

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Alcohol resistant foam dry chemical powder Carbon dioxide Water spray.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Nitrogen oxides Carbon dioxide Carbon monoxide.

5.3. Advice for firefighters

Firefighting instructions	: Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Wear self-contained breathing apparatus, rubber boots and thick rubber gloves.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid raising dust. Ensure adequate ventilation.
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6.1.1. For non-emergency personnel

Protective equipment	: Use the personal protective equipment as indicated in chapter 8.
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6.1.2. For emergency responders

Protective equipment	: Wear suitable protective clothing and eye/face protection.
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6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly. Hose down area with water.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Avoid raising dust and aerosols.
Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area
Keep container tightly closed.
Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Hand protection:

Chemical resistant gloves (according to European standard NF EN 374 or equivalent)

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dustmask with filtertype P2

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 157.2 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: 7 - 8 10% solution
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: > °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Freely soluble in water Freely soluble in glacial acetic acid.
Log Pow	: 1.9
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Product is not explosive.
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong oxidizers

Bases

acids.

10.6. Hazardous decomposition products

In case of fire see chapter 5

At very high temperature: decomposes by releasing irritant gases/vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Tranexamic acid (1197-18-8)	
LD50 oral rat	> 15000 mg/kg
LD50 oral	> mg/kg

Skin corrosion/irritation : Causes skin irritation.

pH: 7 - 8 10% solution

Serious eye damage/irritation : Causes serious eye irritation.

pH: 7 - 8 10% solution

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : May cause respiratory irritation.

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : There are no available data for a classification.

12.2. Persistence and degradability

Tranexamic acid (1197-18-8)	
Persistence and degradability	Biodegradability in water: no data available.

12.3. Bioaccumulative potential

Tranexamic acid (1197-18-8)	
Log Pow	1.9
Bioaccumulative potential	No bioaccumulation data available.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

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

Product/Packaging disposal recommendations : Dispose of contaminated material at an authorized site.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user**. Overland transport**

No data available

- Air transport

No data available

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

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Tranexamic acid is not on the REACH Candidate List

Tranexamic acid is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

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15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

2.2	Precautionary statements (CLP)	Modified	
4.1	First-aid measures after skin contact	Modified	
5.1	Unsuitable extinguishing media	Removed	
5.2	Hazardous decomposition products in case of fire	Added	
7.1	Hygiene measures	Added	
9.1	Melting point	Removed	
11.1	LD50 oral rat	Modified	
12.2	Persistence and degradability	Modified	

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : EP. Supplier. Drugbank.

Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

SDS EU (REACH Annex II) ducheffa nieuwe logo

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.