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# SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

Product name: Tranexamic Acid

Creation date: 16.02.2024, Revision: 16.02.2024, Version: 1.0

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING 1.1 Product identifier Product name Tranexamic Acid Product code [AL00072] 1.2 Relevant identified uses of the substance or mixture and uses advised against Relevant identified uses Raw material for cosmetic products. Uses advised against No information. 1.3 Details of the supplier of the safety data sheet Supplier Farmadria DOO Heroja Pinkija 44 26300 Vršac, Serbia +381695565029 info@avenalab.com 1.4 Emergency Telephone Number Emergency 112 Supplier +381695565029 **SECTION 2: HAZARDS IDENTIFICATION** 2.1 Classification of the substance or mixture Classification according to Regulation (EC) No 1272/2008 (CLP) Skin Irrit. 2; H315 Causes skin irritation. Eye Irrit. 2; H319 Causes serious eye irritation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]



Signal word: WARNING H315 Causes skin irritation. H319 Causes serious eye irritation. P102 Keep out of reach of children. P264 Wash ... thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical advice/attention. P501 Dispose of contents/container in accordance with national regulation.



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PBT/vPvB

No information.

Endocrine disrupting properties

The product does not contain substances with the potential for endocrine disorders.

Additional information

#### No information.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

| For mixtures see 3.2.<br>Mixtures |                             |     |  |                                     |                         |
|-----------------------------------|-----------------------------|-----|--|-------------------------------------|-------------------------|
| Name                              | CAS EC Index<br>Reach       | %   | Classification<br>according to<br>Regulation (EC)<br>No 1272/2008<br>(CLP) | Specific<br>Concentration<br>Limits | Notes for<br>substances |
| Tranexamic Acid                   | 1197-18-8<br>214-818-2<br>- | 100 | Skin Irrit. 2; H315<br>Eye Irrit. 2; H319                                  | 1                                   |                         |

## **SECTION 4: FIRST AID MEASURES**

4.1 Description of first aid measures

General notes

Never give anything by mouth to an unconscious person. Place patient in recovery position and ensure airway patency. When in doubt or if feeling unwell seek medical assistance. Show the safety data sheet and label to the physician.

#### Following inhalation

Remove patient to fresh air - move out of dangerous area. Obtain professional medical help!

Following skin contact

Take off all contaminated clothing. Areas of the body that have come into contact with the product must be rinsed with water. If symptoms develop and persist, seek medical attention.

#### Following eye contact

Immediately flush eyes with running water, keeping eyelids apart. If irritation persists, seek professional medical attention.

Following ingestion

Do not induce vomiting! Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Consult a physician. Show the physician the safety data sheet or label.

4.2 Most important symptoms and effects, both acute and delayed

Following inhalation No information.

Following skin contact Itching, redness, pain.

Following eye contact Redness, tearing, pain.

## Following ingestion

May cause nausea/vomiting and diarrhea. May cause abdominal discomfort. Irritates mucous membranes in the mouth, throat, esophagus and in gastrointestinal area.

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



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| be taken involving any personal risk or without suitable training.            |
| ncluding helmets, protective boots and gloves) (BS EN 469) and self-contained |
|   |
|   |
| lures   |
|   |
|   |
|   |
|   |
| raining. Prevent access to unprotected personnel. Evacuate the danger zone.   |
|   |

6.3 Methods and material for containment and cleaning up

For containment No information.

For cleaning up

Prevent release into the sewer, water, basements or confined areas. Clean contaminated area with plenty of water.

Other information No information.

No momation.

6.4 Reference to other sections See also sections 8 and 13.

# SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Protective measures

Measures to prevent fire

Ensure adequate ventilation.

Measures to prevent aerosol and dust generation Prevent dust formation.

Measures to protect the environment



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ACCORDING TO REGULATION (EC) 1907/2006 Product name: Tranexamic Acid Creation date: 16.02.2024, Revision: 16.02.2024, Version: 1.0 Avoid release to the environment. Other measures No information. Advice on general occupational hygiene Use good personal hygiene practices - wash hands at breaks and when done working with material. Do not eat, drink or smoke while working. Avoid contact with skin, eyes and clothes. Remove contaminated clothes and wash them before reuse. Wear suitable protective equipment; see Section 8. 7.2 Conditions for safe storage, including any incompatibilities Technical measures and storage conditions Keep in a cool, dry and well ventilated place. Keep away from food, drink and animal feeding stuffs. Packaging materials Store only in original container. Requirements for storage rooms and vessels Close opened containers after use. Put the containers upright to prevent from leaking. Do not store in unlabelled containers. Storage temperature No information. Storage class No information. Further information on storage conditions No information. 7.3 Specific end use(s) Recommendations No information. Industrial sector specific solutions No information.

# SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

Occupational Exposure limit values

## No information.

Information on monitoring procedures

BS EN 14042:2003 Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents. BS EN 689:2018 Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values. BS EN 482:2021 Workplace exposure. Procedures for the determination of the concentration of chemical agents. Basic performance requirements.

DNEL/DMEL values

For product No information.

For components

No information.

PNEC values

For product

No information.

For components No information.

8.2 Exposure controls

Appropriate engineering control

Substance/mixture related measures to prevent exposure during identified uses

Use good personal hygiene practices – wash hands at breaks and when done working with material. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothes. Do not eat, drink or smoke while working. Do not breathe dust.

Structural measures to prevent exposure

No information.

Organisational measures to prevent exposure Remove all contaminated clothes immediately and wash them before reuse.

Technical measures to prevent exposure



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Provide good ventilation and local exhaust in areas with increased concentration. Keep away from food, drink and animal feeding stuffs.

#### Personal protective equipment

### Eye and face protection

Tight fitting protective goggles (EN 166).

#### Hand protection

Protective gloves (EN ISO 374-1:2016). Observe the manufacturer's instructions regarding the use, storage, maintenance and replacement of gloves. In case of damage or at the first signs of wear and tear, change the gloves immediately. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. The penetration time is determined by the protective glove manufacturer and must be observed.

Appropriate materials

#### Skin protection

Cotton protective clothing and shoes that cover the entire foot (EN ISO 20345:2022). At high risk of skin exposure chemical suits (EN 13034:2005+A1:2009) and boots may be required (EN ISO 20345:2022).

## Respiratory protection

In case of insufficient ventilation wear suitable respiratory protection. Mask with dust filter (P2) or FFP2 (EN 149:2001+A1:2009).

Thermal hazards

No information.

#### Environmental exposure controls

Substance/mixture related measures to prevent exposure No information.

Instruction measures to prevent exposure No information.

Organisational measures to prevent exposure No information.

#### No information.

Technical measures to prevent exposure

Do not allow product to reach drains, sewage systems or ground water.

## **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

#### 9.1 Information on basic physical and chemical properties

Important health, safety and environmental information

| Physical state   | solid                |
|--|----------------------|
| Shape  | crystalline powder   |
| Colour   | white                |
| Odour  | No information.      |
| Odour threshold  | No information.      |
| Melting/freezing point                                   | > 284 °C             |
| Boiling point or initial boiling point and boiling range | > 284 °C at 1010 hPa |
| Flammability (solid, gas)                                | No information.      |
| Explosion limits (vol%)                                  | No information.      |
| Flash point  | > 120 °C             |
| Auto-ignition temperature                                | > 400 °C             |
| Decomposition temperature                                | 283.5 °C             |
| рН   | 7 — 8                |
| Viscosity  | No information.      |
| Solubility   | No information.      |
| Partition coefficient n-octanol/water (log value)        | No information.      |
|  |                      |



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| Vapour pressure             | No information.                 |
|-----------------------------|---------------------------------|
| Density                     | 1168 kg/m <sup>3</sup> at 20 °C |
| Relative vapour/gas density | No information.                 |
| Particle characteristics    | No information.                 |

9.2 Other information

Information with regard to physical hazard classes No information.

Other safety characteristics

No information.

## SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2 Chemical stability

Product is stable under normal conditions of use, recommended handling and storage conditions.

10.3 Possibility of hazardous reactions No dangerous reactions known under conditions of normal use.

10.4 Conditions to avoid None under recommended storage and handling conditions (see section 7)

10.5 Incompatible materials Strong oxidizing agents.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

(a) Acute toxicity

No information.

Additional information

The product is not classified as acutely toxic.

(b) Skin corrosion/irritation No information.

Additional information

Causes skin and eye irritation.

(c) Serious eye damage/irritation

No information.

(d) Respiratory or skin sensitisation No information.

Additional information The product is not classified as sensitising.

(e) (Germ cell) mutagenicity No information.

(f) Carcinogenicity No information.

(g) Reproductive toxicity No information.



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| ion date: 16.02.2024, Revision: 16.02.2024, Version: 1.0<br>ummary of evaluation of the CMR properties<br>The product for of leasified as cancendingenia, mutagenic or toxic for reproduction.<br>) STOT-single exposure<br>No information.<br>STOT SE (single exposure): Not classified.<br>STOT SE (single exposure): Not classified.<br>STOT File (single exposure): Not classified.<br>STOT File (single exposure): Not classified.<br>STOT File (single exposure): Not classified.<br>Appiration hazard<br>No information.<br>STOT information.   |   | ACCORDING TO REGULATION (EC) 1907/2006             |
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| No information.<br>ioconcentration factor (BCF)<br>No information.<br>Mobility in soil<br>nown or predicted distribution to environmental compartments<br>No information.<br>urface tension<br>No information.<br>dsorption/Desorption<br>No information.  | 2.3 Bioaccumulative potential   |  |
| No information.<br>4 Mobility in soil<br>nown or predicted distribution to environmental compartments<br>No information.<br>urface tension<br>No information.<br>dsorption/Desorption<br>No information.   | No information.   | alue)  |
| nown or predicted distribution to environmental compartments<br>No information.<br>urface tension<br>No information.<br>dsorption/Desorption<br>No information.  | · /   |  |
| No information.<br>urface tension<br>No information.<br>dsorption/Desorption<br>No information.  | 2.4 Mobility in soil  | F I  |
| No information.<br>dsorption/Desorption<br>No information.   |   | imental compartments                               |
| No information.  | Surface tension<br>No information.  |  |
| Recults of PRT and vPvR accossment   | Adsorption/Desorption<br>No information.  |  |
| No evaluation.   | 2.5 Results of PBT and vPvB assessment  |  |
| Endocrine disrupting properties  |   |  |
| The product does not contain substances with the potential for endocrine disorders.  |   |  |



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### Creation date: 16.02.2024, Revision: 16.02.2024, Version: 1.0

12.7 Other adverse effects No information.

12.8 Additional information

For product

Product is not classified as dangerous for environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product / Packaging disposal

### Waste chemical

Do not allow product to reach drains/sewage systems. Disposal must be made according to official regulations: deliver it to authorised collector/remover/transformer of hazardous waste.

Waste codes / waste designations according to LoW No information.

### Packaging

Deliver completely emptied containers to approved waste disposal authorities. Uncleaned containers are classified as hazardous waste - they should be handled in the same manner as the contents.

Waste codes / waste designations according to LoW No information.

Waste treatment-relevant information No information.

Sewage disposal-relevant information No information.

Other disposal recommendations No information.

## **SECTION 14: TRANSPORT INFORMATION**

| ADR/RID   | IMDG  | ΙΑΤΑ  | ADN   |
|---|---|---|---|
| 14.1 UN number or ID number                       |   |   |   |
| Not dangerous according to transport regulations. |
| 14.2 UN proper shipping name                      |   |   |   |
| Not given/not applicable                          | Not given/not applicable                          | Not given/not applicable                          | Not given/not applicable                          |
| 14.3 Transport hazard class(es)                   |   |   |   |
| Not given/not applicable                          | Not given/not applicable                          | Not given/not applicable                          | Not given/not applicable                          |
| 14.4 Packing group                                |   |   |   |
| Not given/not applicable                          | Not given/not applicable                          | Not given/not applicable                          | Not given/not applicable                          |
| 14.5 Environmental hazards                        |   |   |   |
| NO  | NO  | NO  | NO  |



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| ADR/RID  | IMDG   | ΙΑΤΑ | ADN  |
|--|--|------|--|
| 14.6 Special precautions for user                                  |  |      |  |
| Limited quantities<br>Not given/not applicable                     | Limited quantities<br>Not given/not applicable |      | Limited quantities<br>Not given/not applicable |
| 14.7 Maritime transport in<br>bulk according to IMO<br>instruments |  |      |  |
|  | Not given/not applicable                       |      |  |

## SECTION 15: REGULATORY INFORMATION

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

- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (including last amendment Commission Regulation (EU) 2020/878)

- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

Information according 2004/42/EC about limitation of emissions of volatile organic compounds (VOC-guideline) not applicable

Ingredients according to Regulation (EC) No 648/2004 on detergents

No information.

Special instructions

Observe the regulations on employment and protection against dangerous substances for young people, pregnant women and nursing mothers.

#### 15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

## **SECTION 16: OTHER INFORMATION**

Indication of changes

No information.

Key literature references and sources for data No information.

Abbreviations and acronyms

- ATE Acute Toxicity Estimate
- ADR Agreement concerning the International Carriage of Dangerous Goods by Road
- ADN European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
- CEN European Committee for Standardisation
- C&L Classification and Labelling
- CLP Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
- CAS# Chemical Abstracts Service number
- CMR Carcinogen, Mutagen, or Reproductive Toxicant
- CSA Chemical Safety Assessment
- CSR Chemical Safety Report
- DMEL Derived Minimal Effect Level
- DNEL Derived No Effect Level
- DPD Dangerous Preparations Directive 1999/45/EC DSD - Dangerous Substances Directive 67/548/EEC
- DU Downstream User
- EC European Community
- ECHA European Chemicals Agency
- EC-Number EINECS and ELINCS Number (see also EINECS and ELINCS)
- EEA European Economic Area (EU + Iceland, Liechtenstein and Norway)
- EEC European Economic Community



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ACCORDING TO REGULATION (EC) 1907/2006

Product name: Tranexamic Acid Creation date: 16.02.2024, Revision: 16.02.2024, Version: 1.0 EINECS - European Inventory of Existing Commercial Substances ELINCS - European List of notified Chemical Substances EN - European Standard EQS - Environmental Quality Standard EU - European Union Euphrac - European Phrase Catalogue EWC - European Waste Catalogue (replaced by LoW - see below) GES - Generic Exposure Scenario GHS - Globally Harmonized System IATA - International Air Transport Association ICAO-TI - Technical Instructions for the Safe Transport of Dangerous Goods by Air IMDG - International Maritime Dangerous Goods IMSBC - International Maritime Solid Bulk Cargoes IT - Information Technology IUCLID - International Uniform Chemical Information Database IUPAC - International Union for Pure Applied Chemistry JRC - Joint Research Centre Kow - octanol-water partition coefficient LC50 - Lethal Concentration to 50 % of a test population LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose) LE - Legal Entity LoW - List of Wastes (see http://ec.europa.eu/environment/waste/framework/list.htm) LR - Lead Registrant M/I - Manufacturer / Importer MS - Member States MSDS - Material Safety Data Sheet **OC** - Operational Conditions OECD - Organization for Economic Co-operation and Development **OEL** - Occupational Exposure Limit OJ - Official Journal **OR** - Only Representative OSHA - European Agency for Safety and Health at work PBT - Persistent, Bioaccumulative and Toxic substance PEC - Predicted Effect Concentration PNEC(s) - Predicted No Effect Concentration(s) PPE - Personal Protection Equipment (Q)SAR - Qualitative Structure Activity Relationship REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 RID - Regulations concerning the International Carriage of Dangerous Goods by Rail **RIP - REACH Implementation Project** RMM - Risk Management Measure SCBA - Self-Contained Breathing Apparatus SDS - Safety data sheet SIEF - Substance Information Exchange Forum SME - Small and Medium sized Enterprises STOT - Specific Target Organ Toxicity (STOT) RE - Repeated Exposure (STOT) SE - Single Exposure SVHC - Substances of Very High Concern **UN - United Nations** vPvB - Very Persistent and Very Bioaccumulative List of relevant H phrases H315 Causes skin irritation. H319 Causes serious eye irritation.