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

### **1.1. Product identifier:**

Trade name: Skinitril  
UFI code: V700-FU65-550T-QDNC

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

#### Relevant identified uses:

- medical device intended for the removal of molluscum contagiosum, condylomas (genital warts) and cutaneous fibromas (benign skin tags).

#### Uses advised against:

Not recommended for other uses than is mentioned.

### **1.3. Details of the supplier of the safety data sheet:**

ENE Pharmaceuticals s. r. o.  
Pražská 442  
281 67 Stříbrná Skalice  
Česká republika  
tel.: +420 705 601 257  
e-mail: info@eneo.cz

### **1.4. Emergency telephone number:**

#### **TOXICOLOGICAL INFORMATION CENTRE,**

Department of Occupational Medicine, GUH in Prague and FFM, Charles University  
Tel.: +420 224 919 293, +420 224 915 402 e-mail: tis@vfn.cz

## **SECTION 2: HAZARDS IDENTIFICATION**

### **2.1. Classification of the substance or mixture:**

Mixture is classified as dangerous according to the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

**Skin Corr. 1A H314; Acute Tox. 3 H331**

### **2.2. Label elements:**



#### **Danger**

H314 Causes severe skin burns and eye damage.

H331 Toxic if inhaled.

P102 Keep out of reach of children.

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P310 Immediately call a POISON CENTER/doctor.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P501 Dispose of contents/container in accordance with applicable regulations.

### **2.3. Other hazards:**

EUH071 Corrosive to the respiratory tract.

The mixture does not contain substances meeting the criteria for PBT or vPvB.

The mixture does not contain substances identified as endocrine disruptors.

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### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.2. Mixture:

| CAS                                                                          | EC        | Registration nr. | Classification                                                       | Spec. Conc. Limits, M-factors and ATEs                                                                                                                     | Content (%) |
|------------------------------------------------------------------------------|-----------|------------------|----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| <sup>2</sup> Nitric acid                                                     |           |                  |                                                                      |                                                                                                                                                            |             |
| 7697-37-2                                                                    | 231-714-2 | 01-2119487297-23 | Ox. Liq. 3 H272<br>Skin Corr. 1A H314<br>Acute Tox. 3 H331<br>EUH071 | Ox. Liq. 3 H272:<br>C ≥ 65 %<br>Skin Corr. 1A H314:<br>C ≥ 20 %<br>Skin Corr. 1B H314:<br>5 % ≤ C < 20 %<br>ATE inhalation:<br>2,65 mg/l (vapour)          | 60 - < 65   |
| <sup>1</sup> Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer |           |                  |                                                                      |                                                                                                                                                            |             |
| 111286-86-3                                                                  | 601-067-4 | --               | --                                                                   | --                                                                                                                                                         | 4 - < 6     |
| Acetic acid                                                                  |           |                  |                                                                      |                                                                                                                                                            |             |
| 64-19-7                                                                      | 200-580-7 | 01-2119475328-30 | Flam. Liq. 3 H226<br>Skin Corr. 1A H314                              | Skin Corr. 1A H314:<br>C ≥ 90 %<br>Skin Corr. 1B H314:<br>25 % ≤ C < 90 %<br>Skin Irrit. 2H315:<br>10 % ≤ C < 25 %<br>Eye Irrit. 2H319:<br>10 % ≤ C < 25 % | 3 - < 5     |
| <sup>1</sup> Oxalic acid dihydrate                                           |           |                  |                                                                      |                                                                                                                                                            |             |
| 6153-56-6                                                                    | 612-167-2 | --               | Acute Tox. 4 H312<br>Acute Tox. 4 H302                               | --                                                                                                                                                         | 3 - < 5     |

#### Notes:

\*Full text H - phrases is referred to in point 16.

<sup>1</sup>Substance is not classified according to Regulation (EC) No. 1272/2008 (CLP).

<sup>2</sup>Substance for which an occupational exposure limit has been established.

### SECTION 4: FIRST AID MEASURES

#### 4.1. Description of first aid measures:

**Inhalation:** Remove the affected person to fresh air. Keep the affected person warm and at rest in an upright position. If breathing has stopped or shows signs of respiratory failure, provide artificial respiration. Mouth-to-mouth resuscitation may be dangerous.

**Skin contact:** Thoroughly rinse the affected area with plenty of water. Remove contaminated clothing and footwear. Continue rinsing for at least 15 minutes. Chemical burns must be treated promptly by a physician.

**Eye contact:** Immediately flush eyes with an eye wash solution or clean water for at least 15 minutes.

**Ingestion:** Do not induce vomiting. If the affected person is conscious, rinse the mouth with water and give water or milk to drink. Seek immediate medical attention.

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

Causes severe skin burns and eye damage. Toxic if inhaled.

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

No specific treatment is known. Use support and symptomatic treatment.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1. Extinguishing media:

The product is not flammable. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Suitable extinguishing media:**

Water spray, carbon dioxide (CO<sub>2</sub>).

**Unsuitable extinguishing media:**

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Do not use dry chemical extinguishing agents or foam. Do not attempt to extinguish the fire with steam or sand.

**5.2. Special hazards arising from the substance or mixture:**

Contact with strong reducing agents may result in a violent reaction. Contact with common metals may produce hydrogen gas, which can form explosive mixtures with air.

**5.3. Advice for firefighters:**

Evacuate the fire area. If it can be done safely, remove containers from the vicinity of the fire to a safe location. Cool fire-exposed containers with water spray. When fighting a fire, wear acid-resistant impermeable protective clothing, a full-face mask and a self-contained breathing apparatus (SCBA). Approach the fire from the upwind side. Prevent fire-fighting water from entering sewers, drains or watercourses. Contaminated fire-fighting water must be contained, collected and disposed of in accordance with applicable regulations.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

**6.1. Personal precautions, protective equipment and emergency procedures:**

Ensure adequate ventilation. Avoid direct contact with the spilled product by using appropriate personal protective equipment (see Section 8). If it is safe to do so, stop further leakage and prevent the spread of the product. Prevent entry into sewers, drains and water sources.

**6.2. Environmental precautions:**

In the event of a large-scale release of the product into the environment, inform the relevant authorities.

**6.3. Methods and material for containment and cleaning up:**

Ensure adequate ventilation in the spill area. Small spills should be diluted with water and carefully neutralized using soda ash or lime prior to disposal. Large spills should be contained and covered with sand or earth, where necessary. Do not use organic materials, sawdust, or similar absorbents. If possible, isolate the source of the release immediately. Collect the absorbed material mechanically and transfer it to a suitable, properly labelled container for disposal.

**6.4. Reference to other sections:**

For information on personal protective equipment, see Section 8.

For information on disposal considerations, see Section 13.

**SECTION 7: HANDLING AND STORAGE**

**7.1. Precautions for safe handling:**

Ensure adequate ventilation of working areas. Observe safe handling procedures and good occupational hygiene practices when handling the product. Only trained personnel should handle this product. Wear appropriate personal protective equipment during handling. Wash hands thoroughly after handling. Contaminated work clothing should be cleaned thoroughly before reuse. Eating, drinking and smoking are prohibited while handling the product.

**7.2. Conditions for safe storage, including any incompatibilities:**

Store in tightly closed containers in a cool, dry and well-ventilated place. Protect from direct sunlight. Recommended storage temperature: 5 - 25 °C.

Do not store together with food, beverages, feedingstuffs or their containers. Keep away from incompatible materials.

**7.3. Specific end use(s):**

See point 1.2.

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

**8.1. Control parameters:**

Indicative occupational exposure limit values (IOELVs) for the protection of workers from chemical risks according to the Directive 98/24/EC. No occupational exposure limits have been established for this mixture.

| EC | CAS | Name of agent | Limit values |            | Notation |
|----|-----|---------------|--------------|------------|----------|
|    |     |               | 8 hours      | Short term |          |

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| 231-714-2        | 7697-37-2                 | Nitric acid     | -- -- 2.6 1 --          |

**DNEL values for workers**

| Effect                  | Route of exposure | Value                 |
|-------------------------|-------------------|-----------------------|
| Acute local effects     | Inhalation        | 2.6 mg/m <sup>3</sup> |
| Long-term local effects | Inhalation        | 2.6 mg/m <sup>3</sup> |

**DNEL values for consumers**

|                         |            |                       |
|-------------------------|------------|-----------------------|
| Acute local effects     | Inhalation | 1.3 mg/m <sup>3</sup> |
| Long-term local effects | Inhalation | 1.3 mg/m <sup>3</sup> |

**8.2. Exposure controls:**

Provide adequate local exhaust ventilation where necessary. Safety showers and eyewash stations should be available in all areas where exposure to the eyes or skin may occur. Do not eat, drink or smoke while handling the product. Wash hands thoroughly after handling and before eating, smoking, using the toilet, and at the end of each work shift.

The choice of appropriate personal protective equipment should be based on the handling conditions, the nature of the product and the potential duration of exposure.

**a) Eye/face protection:**

If there is a risk of splashing, wear tightly fitting chemical safety goggles or a face shield.

**b) Skin protection:**
**I. Hand protection:**

Use suitable protective gloves. Consult the glove supplier when selecting an appropriate glove material. The glove material should be resistant to acids. Replace damaged gloves immediately.

**II. Other:**

Wear acid-resistant protective clothing and acid-resistant safety footwear.

**c) Respiratory protection:**

Where vapour/aerosol concentrations are elevated or ventilation is inadequate, wear a respirator equipped with a suitable acid gas filter. Use suitable respiratory protective equipment or a self-contained breathing apparatus (SCBA) where exposure limits are exceeded or may be exceeded.

**d) Thermal hazards:**

Not required.

**Environmental exposure controls:**

Prevent the release of the product into the environment by all available means.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**9.1. Information on basic physical and chemical properties:**

|                                                           |                                                                   |
|-----------------------------------------------------------|-------------------------------------------------------------------|
| Physical state:                                           | viscous liquid.                                                   |
| Colour:                                                   | Opalescent to milky white                                         |
| Odour:                                                    | vinegar-like                                                      |
| Melting point/freezing point:                             | -20 °C at 1013 hPa (60% nitric acid solution)*                    |
| Boiling point or initial boiling point and boiling range: | 120 °C at 1013 hPa (60% nitric acid solution)*                    |
| Flammability:                                             | Non-flammable                                                     |
| Lower and upper explosion limit:                          | Non-flammable                                                     |
| Flash point:                                              | Not relevant (inorganic substance).                               |
| Auto-ignition temperature:                                | Information is not available.                                     |
| Decomposition temperature:                                | 83 °C at 1013 hPa (60% nitric acid solution)*                     |
| pH:                                                       | <1 (60% nitric acid solution)*                                    |
| Kinematic viscosity:                                      | Information is not available.                                     |
| Solubility:                                               | in water: 500 g/L at 20 °C*<br>Miscibility with water: unlimited. |
| Partition coefficient n-octanol/water (log value):        | Information is not available.                                     |

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Vapour pressure: Information is not available.  
Density and/or relative density: 1.31 g/cm<sup>3</sup>  
Relative vapour density: 2 (relative to air)\*  
Particle characteristics: Not applicable.

**9.2. Other information:**

No further information available.

\*Source: ECHA Registered Substances Database.

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**SECTION 10: STABILITY AND REACTIVITY**

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**10.1. Reactivity:**

The product is not reactive under normal conditions of use and storage.

**10.2. Chemical stability:**

Chemically stable under the prescribed storage conditions.

**10.3. Possibility of hazardous reactions:**

May react violently with reducing agents, strong bases, organic materials, chlorides and finely divided metals. Reacts exothermically with water.

**10.4. Conditions to avoid:**

High temperatures, light and contamination.

**10.5. Incompatible materials:**

Reducing agents; alkaline and corrosive substances; metal dust; hydrogen sulfide; chlorates; carbonates; non-noble metals; alcohols.

**10.6. Hazardous decomposition products:**

Exposure of nitric acid to heat may generate nitrogen oxides (NO<sub>x</sub>).

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**SECTION 11: TOXICOLOGICAL INFORMATION**

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

**a) acute toxicity:**

Toxic if inhaled.

For nitric acid:

Inhalation:

Rat (Wistar), male/female; OECD 403:

LC50 (4 h): > 2.65 mg/L air

Rat (CRL:CD BR), male/female; study similar to OECD 403:

LC50 (1 h): approx. 2,500 ppm

Source: ECHA Registered Substances Database.

**b) skin corrosion/irritation:**

Causes severe skin burns.

**c) serious eye damage/irritation:**

Causes serious eye damage.

**d) respiratory or skin sensitisation:**

Based on available data, the classification criteria are not met.

**e) germ cell mutagenicity:**

Based on available data, the classification criteria are not met.

**f) carcinogenicity:**

Based on available data, the classification criteria are not met.

**g) reproductive toxicity:**

Based on available data, the classification criteria are not met.

**h) STOT-single exposure:**

Based on available data, the classification criteria are not met.

**i) STOT-repeated exposure:**

Based on available data, the classification criteria are not met.

**j) aspiration hazard:**

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Based on available data, the classification criteria are not met.

**11.2. Information on other hazards:**

No other information regarding hazards to human health is available.

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1. Toxicity:**

No information on the toxicity of the mixture is available.

For nitric acid:

Acute/chronic toxicity to fish:

Median lethal pH (96 h): 3.0 - 3.5 for *Lepomis macrochirus* (no guideline method reported).

Median lethal pH (96 h): approximately 3.7 for *Oncorhynchus mykiss* (no guideline method reported).

Acute/chronic toxicity to aquatic invertebrates:

48-hour LC50 (pooled analysis) for *Ceriodaphnia dubia* (USEPA method): pH 4.6.

General effects:

Effects are related to changes in pH. Increased nitrate concentrations may cause secondary adverse effects.

**Source:** ECHA Registered Substances Database.

**12.2. Persistence and degradability:**

Information is not available.

**12.3. Bioaccumulative potential:**

Information is not available.

**12.4. Mobility in soil:**

Information is not available.

**12.5. Results of PBT and vPvB assessment:**

The mixture does not contain components meeting the criteria for PBT or vPvB substances.

**12.6. Endocrine disrupting properties:**

The mixture does not contain components identified as endocrine disruptors.

**12.7. Other adverse effects:**

Release of large quantities into the environment may reduce the pH of the aquatic environment.

**SECTION 13: DISPOSAL CONSIDERATIONS**

**13.1. Waste treatment methods:**

Carefully neutralise with lime or carbonates.

Dispose of in accordance with applicable legislation.

The packaging is intended solely for this product. After use, completely empty the containers and dispose of them through authorised waste management facilities.

Waste classification according to the Waste Catalogue:

Unused or contaminated product:

**06 01 05\*** Nitric acid and nitrous acid (Hazardous waste)

Contaminated packaging:

**15 01 10\*** packaging containing residues of or contaminated by hazardous substances

**SECTION 14: TRANSPORT INFORMATION**

**14.1. UN number or ID number:** 2031

**14.2. UN proper shipping name:** NITRIC ACID, other than red fuming, with not more than 65% nitric acid

**14.3. Transport hazard class(es):** 8

**14.4. Packing group:** II

**14.5. Environmental hazards:** Product is not classified as hazardous to the environment according to ADR/RID Code.

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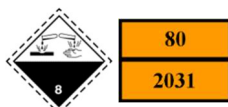
**14.6. Special precautions for user:** The regulations applicable to the respective mode of transport shall be observed.

**14.7. Maritime transport in bulk according to IMO instruments:** Not applicable.

**Classification code:** C1

**Hazard identification number:** 80

**Hazard labels:**



## SECTION 15: REGULATORY INFORMATION

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

Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and as amended;  
 Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 and as amended;

Commission regulation (EU) 2020/878 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work and as amended;

Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives;

Commission decision replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste.

### 15.2. Chemical safety assessment:

Chemical safety assessment has been carried out for individual components of the product.

## SECTION 16: OTHER INFORMATION

### Changes made in the revision:

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### Used information sources:

Safety data sheets provided by suppliers of the individual components of the product.

**Source:** European Chemicals Agency (ECHA), Registered Substances Database:

<https://chem.echa.europa.eu/100.028.832/overview?searchText=nitric%20acid>

### List of relevant hazards statements:

H314 Corrosive to the respiratory tract.

H226 Flammable liquid and vapour.

H272 May intensify fire; oxidiser.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H314 Causes severe skin burns and eye damage.

H331 Toxic if inhaled.

### Instructions for the training:

Training in the safe handling of the product shall form part of the occupational health and safety training programme (initial training, workplace training and refresher training), taking into account the specific conditions of the workplace.

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This Safety Data Sheet has been prepared on the basis of the available information and knowledge of the product itself as of the date of issue of this Safety Data Sheet.

**- End of Safety Data Sheet -**