# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## ACIDUM LACTICUM



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Version: 00

MAGIS PHARMA

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

### 1.1 Product identifier

| | |
|---|---|
| Product name: | Lactic acid |
| | Acidum lacticum |
| | Melkzuur |
| | Lactique (acide) |
| | Milchsäure |
| N° CAS: | 79-33-4 |
| N° EC: | 201-196-2 |

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

| | |
|---|---|
| Identified uses: | Active Pharmaceutical Ingredient or Excipient. |

### 1.3 Details of the supplier of the safety data sheet

| | |
|---|---|
| Company: | FAC SECUNDUM ARTEM NV |
| | Oostmalsebaan 1c (unit 5) |
| | 2960 Sint-Lenaarts |
| | 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 Irrit. 2 | H315 |
| Eye Dam. 1 | H318 |

### 2.2 Label elements

**Labelling according to (EC) n° 1272/2008**

Hazard pictogram(s):

Signal word(s): Danger

Hazard statements:

| | |
|---|---|
| H315 | Causes skin irritation. |
| H318 | Causes serious eye damage. |

Precautionary statements:

| | |
|---|---|
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| P310 | Immediately call a POISON CENTER or doctor. |
| P321 | Specific treatment (see on this label). |

| | |
|---|---|
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P362 | Take off contaminated clothing. |
| P332+P313 | If skin irritation occurs: Get medical advice/attention. |
| Additional applicable label elements: | Not applicable. |

### 2.3 Other hazards

None.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

| | |
|---|---|
| Product name: | Lactic acid |
| IUPAC name: | (2S)-2- Hydroxypropanoic acid |
| Synonyms: | L-(+)-Lactic acid |
| | L-Lactic acid |
| | (S)-(+)-Lactic acid |
| | (S)-Lactic acid |
| N° CAS: | 79-33-4 |
| N° EC: | 201-196-2 |
| Molecular Formula: | $C_3H_6O_3$ |
| Content: | 88.0 per cent *m/m* to 92.0 per cent *m/m* of $C_3H_6O_3$ |

Mixture of 2-hydroxypropanoic acid, its condensation products, such as lactoyl-lactic acid and polylactic acids, and water. The equilibrium between lactic acid and polylactic acids depends on the concentration and temperature. It is usually the racemate ((RS)-lactic acid).

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

| | |
|---|---|
| General notes: | Consult a doctor. Show the safety data sheet to the doctor on duty. |
| After inhalation: | Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision. |
| After skin contact: | Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists. |
| After eye contact: | Remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Get medical attention. |
| After ingestion: | If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately. |

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

For symptoms and effects due to substances, see section 11.

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

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

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

| | |
|---|---|
| Suitable extinguishing media: | Foam, dry powder, carbon dioxide, sand, water mist. |
| | Neighbouring fires (containers exposed to fire): Water spray or fog. |
| Unsuitable extinguishing media: | Direct water jet. |

### 5.2 Special hazards arising from the substance/mixture

Avoid inhalation of combustion products (carbon oxides, toxic pyrolysis products, etc.). The product is combustible and, when dusts are dispersed in air in sufficient concentrations, and in the presence of an ignition source, may give explosive mixtures with air. Fire may grow or be further ignited by the solid, by removing containers when elevated temperatures are reached or by contact with ignition sources.

### 5.3 Advice for firefighters

| | |
|---|---|
| Surrounding fires: | Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water that should not enter the sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations. |
| Protection against fire: | Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137). |
| Hazardous combustion products: | Not available. |

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel**

Eliminate sources of ignition (cigarettes, flames, sparks, etc.) or heat from the area where the leak occurred. Avoid dust, spray with water, if there are no contraindications.

In case of airborne dust, use respiratory protection. Stop leak if there is no risk. Do not handle damaged or spilled containers unless wearing appropriate protective equipment. For more information on environmental and health hazards, respiratory protection, ventilation and personal protective equipment, see other sections of this sheet.

**For emergency responders**

Eliminate sources of ignition (cigarettes, flames, sparks, etc.) or heat from the area where the leak occurred. Avoid dust, spray with water, if there are no contraindications.

In case of airborne dust, use respiratory protection. Stop leak if there is no risk. Do not handle damaged or spilled containers unless wearing appropriate protective equipment. For more information on environmental and health hazards, respiratory protection, ventilation and personal protective equipment, see other sections of this sheet.

### 6.2 Environmental precautions

Prevent product from entering sewers, surface water, ground water and neighbouring areas.

### 6.3 Methods and material for containment and cleaning up

Absorb spilled product with inert absorbent material (sand, vermiculite, diatomaceous earth, diatomaceous earth, etc.). Sweep up most of the material and place it in containers for disposal. Dispose of waste with water if there are no contraindications. Ensure adequate ventilation of the leakage site. Disposal of contaminated material should be in accordance with section 13.

### 6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

| | |
|---|---|
| Precautions for safe handling: | Not available. |
| Personal protection: | For personal protection, see section 8. |
| Technical protective measures: | Not available. |
| Handling: | Not available. |

### 7.2 Conditions for safe storage, including any incompatibilities

| | |
|---|---|
| Storage: | The product does not require special storage measures. |
| Conditions for safe storage, including any incompatibilities: | Keep containers tightly closed, in a cool, dry place, away from flames and sparks. |
| Storage – away from: | Not available. |

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Not available.

### 8.2 Exposure controls

**Appropriate engineering control**

Since the use of appropriate technical measures must always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction.

When choosing personal protective equipment, ask your chemical suppliers if this is necessary.

Personal protective equipment must be CE-marked for compliance with applicable regulations.

Provide an emergency shower with a viscoelastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

**Individual protection measures**

| | |
|---|---|
| Eye/face protection: | Protective face shields and safety goggles according to EN166. |
| Skin protection: | Choose body protection according to the quantity and concentration of the hazardous substance in the workplace. |
| Hand protection: | Handle with gloves.<br>The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard. |
| Respiratory protection: | Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143).<br>Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU). |
| 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: | Colourless or slightly yellow, syrupy liquid. |
| Odour: | Not available. |
| Odour threshold: | Not available. |
| pH: | (1%): 4.5 - 6.0 |
| Melting/freezing point: | Not available. |
| Initial boiling point: | 125 °C |
| Boiling range: | Not available. |
| Flash point: | 112 °C |
| 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: | 1.20 to 1.21 g/mL |
| Solubility: | Miscible with ethanol (96 per cent). |
| Solubility in water: | Miscible with water. |
| Partition coefficient (n-octanol/water): | LogPow -0.62 (20 °C) |
| Auto-ignition temperature: | Not available. |
| Decomposition temperature: | Not available. |
| Viscosity: | 60 mPa·s (25 °C) |
| Explosive properties: | Not available. |
| Oxidising properties: | Not available. |

### 9.2 Other information

Molecular weight: 90.01 g/mol

Density (25 °C): 1.215 g/mL

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

No special conditions. Stable under the recommended handling and storage conditions (see section 7).

### 10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

### 10.3 Possibility of hazardous reactions

Under normal conditions of use and storage, hazardous reactions are not predictable.

### 10.4 Conditions to avoid

None in particular. However, follow the usual precautions against chemicals.

### 10.5 Incompatible materials

Not available.

### 10.6 Hazardous decomposition products

When heated or in the event of fire it can release gases and vapours that are hazardous to health.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

| | |
|---|---|
| Acute toxicity: | Acute oral toxicity ($LD_{50}$, rat): 4875 mg/kg |
| | Acute inhalation toxicity ($LD_{50}$, rat): 7.94 mg/L/4 hr. |
| | Acute dermal toxicity ($LD_{50}$, rabbit): > 2000 mg/kg |
| Skin corrosion/irritation: | May cause skin irritation. |
| Serious eye damage/irritation: | May cause eye irritation. |
| Respiratory/skin sensitisation: | May cause respiratory irritation. |
| Germ cell mutagenicity: | Not available. |
| Carcinogenicity: | No component of this product is identified as a probable, possible or confirmed human carcinogen at levels greater than or equal to 0.1%. |
| Reproductive toxicity: | Not available. |
| Summary of evaluation of the CMR properties: | Not available. |
| STOT-single exposure: | Not available. |
| STOT-repeated exposure: | Not available. |
| Aspiration Hazard: | Not available. |
| Other: | Not available. |

### 11.2 Additional information on potential adverse human health effects and symptoms

| | |
|---|---|
| Eye contact: | May cause severe eye damage and may cause corneal opacity, iris lesions, irreversible eye discolouration. |
| Skin contact: | Harmful if absorbed through skin. May cause irritation, erythema, oedema, dryness and cracked skin. |
| Inhalation: | Harmful if inhaled. May cause moderate upper respiratory tract irritation. |
| Ingestion: | Harmful if swallowed. May cause health problems, including stomach pain with heartburn, nausea and vomiting. |
| Aspiration: | Not available. |

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Toxicity ($EC_{10}$, crustaceans): 240 mg/L/48 hours *Daphnia magna*

### 12.2 Persistence and degradability

Not available.

### 12.3 Bioaccumulative potential

Not available.

### 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

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: Dispose of as unused product.

## 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) : | It is not dangerous in transport. |

### 14.2 UN proper shipping name

| | |
|---|---|
| ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : | It is not dangerous in transport. |

### 14.3 Transport hazard class(es)

| | |
|---|---|
| ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : | It is not dangerous in transport. |

### 14.4 Packing group

| | |
|---|---|
| ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : | It is not dangerous in transport. |

### 14.5 Environmental hazards

| | |
|---|---|
| ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : | It is not dangerous in transport. |

### 14.6 Special precautions for user

It is not dangerous in transport.

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

Not available.

### 14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

Corrosive

Risk phrases:

R38 Irritating to skin.

R41 Risk of serious damage to eyes.

| | |
|---|---|
| Safety phrases: | S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.<br>S27 Take off immediately all contaminated clothing.<br>S36/37/39 Wear suitable protective clothing, gloves and eye/face protection. |

**15.2 Chemical safety assessment**

A chemical safety assessment of the product has not been carried out.

## SECTION 16: OTHER INFORMATION

**16.1 Changes since the previous version**

Not applicable.

**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 Bioaccumalative |

**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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