

ACIDUM AZELAICUM

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Revision: XX/XX/XXXX
Version: 00

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

1.1 PRODUCT IDENTIFIER

Product name: EN: Azelaic acid
LAT: Acidum azelaicum
NL: Azelaïnezuur
FR: Acide azélaïque
DE: Azelainsäure
N° CAS: 123-99-9
N° EC: 204-669-1

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: 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 Irrit. 2 H315
Eye Irrit. 2 H319

2.2 LABEL ELEMENTS

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary statements:

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P264	Wash thoroughly after handling.
P264+P265	Wash thoroughly after handling. Do not touch eyes.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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.
Additional applicable label elements:	Not applicable.

2.3 OTHER HAZARDS

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

Product name:	Azelaic acid
IUPAC name:	1,7-Heptanedicarboxylic acid
Synonyms:	1,7-Heptanedicarboxylic acid 1,9-Nonanedioic acid Anchoic acid Azelex Emerox 1110 Emerox 1144 Finacea Heptanedicarboxylic acid Lepargylic acid Skinoren
N° CAS:	123-99-9
N° EC:	204-669-1
Molecular Formula:	C ₉ H ₁₆ O ₄
Content:	Azelaic acid contains a minimum of 99.0 and a maximum of 101.0 percent non-anhydrous acid, calculated on the anhydrous substance.

3.2 MIXTURES

It does not contain other components or impurities that may influence the classification of the product.

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General notes:	Consult a physician. 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.

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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, also under 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

Causes serious eye irritation. Causes skin irritation.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

Do not administer anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

SECTION 5: FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

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

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE/MIXTURE

In case of fire, fumes harmful to health may be produced.

5.3 ADVICE FOR FIREFIGHTERS

Surrounding fires:	Cool containers with water to avoid product decomposition and the development of potential health hazards. Always use complete fire protection. Collect water from entering sewage system. Dispose of contaminated water used to extinguish and the remains of the second in accordance with current regulations.
Protection against fire:	Helmet with visor, flame retardant clothing (jacket and pants with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the entire face of the operator or the car (self-protector) in the 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

For exposure control and personal protective measures, see section 8.
Equip clean-up personnel with appropriate protective equipment. Ventilate the area

FOR EMERGENCY RESPONDERS

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

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Equip clean-up personnel with appropriate protective equipment. Ventilate the area

6.2 ENVIRONMENTAL PRECAUTIONS

Prevent release to the environment. Prevent it from entering sewers and water pipes. If product enters sewers or public waterways, notify authorities.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Store away from other materials. If on the ground, sweep or scoop (shovel or similar) into suitable containers. Limit dust production.

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:	Wash thoroughly after handling. Do not eat, drink or smoke while handling this product. Ask for special instructions before use.
Personal protection:	Not available.
Technical protective measures:	Ensure good ventilation of the processing area to avoid vapor formation.
Handling:	Not available.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Storage:	Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.
Conditions for safe storage, including any incompatibilities:	Not available.
Storage – away from:	Not available.

7.3 SPECIFIC END USE(S)

Active Pharmaceutical Ingredient.

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 means of effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must bear the CE marking attesting to compliance with applicable regulations. Provide an emergency shower with a visco-elastic tray.

Hygiene measures: Handle with appropriate industrial hygiene precautions and observe safety practices. Wash hands before breaks and after the end of the workday.

INDIVIDUAL PROTECTION MEASURES

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Eye/face protection:	Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (USA) or CEN (EU).
Skin protection:	Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.
Hand protection:	Protective face shields and safety goggles according to EN166.
Respiratory protection:	Choose body protection according to the amount and concentration of the hazardous substance in the workplace.
Thermal hazards:	Not determined.

ENVIRONMENTAL EXPOSURE CONTROL

Total solids (250 oC): 100.00 %
VOC (Directive 2010/75/EC): 0
VOC (Volatile carbon): 0

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White to almost white powder occurring in various crystal forms.
Odour:	Characteristic.
Odour threshold:	Not available.
pH:	The pKa values are 4.5 and 5.4
Melting/freezing point:	107 to 110 °C
Initial boiling point:	357 °C
Boiling range:	Not available.
Flash point:	180 °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:	Not available.
Solubility:	Easily soluble in ethanol 96% and in methanol, soluble in macrogol 400 and in propylene glycol.
Solubility in water:	Poorly soluble in water. 2.4 g/L (20 °C)
Partition coefficient (n-octanol/water):	1.57 (20 °C)
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.

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Explosive properties: Not available.

Oxidising properties: Not available.

9.2 OTHER INFORMATION

Molecular weight (g/mol): 188.22

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY

No special conditions. Stable under 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

Not established.

10.4 CONDITIONS TO AVOID

Avoid any type of incorrect handling: high pressures and/or temperatures. Direct sunlight.

10.5 INCOMPATIBLE MATERIALS

Strong oxidizing agents and strong bases.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Fumes. Carbon monoxide. Carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity: Acute oral toxicity (LD₅₀, rat): > 5000 mg/kg

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: Causes serious eye irritation.

Respiratory/skin sensitisation: Causes skin 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: Not available.

Skin contact: Not available.

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Inhalation: Not available.
Ingestion: Harmful if swallowed.
Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 TOXICITY

EC₅₀ (algae/aquatic plants): > 100 mg/L/72 hours (OECD 201)

12.2 PERSISTENCE AND DEGRADABILITY

Potentially biodegradable substance.

12.3 BIOACCUMULATIVE POTENTIAL

Octanol/water partition coefficient (20 °C): 1.57

BCF: 3.162

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 to dispose 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), It is not dangerous in transport.
IATA/ICAO (Air) :

14.2 UN PROPER SHIPPING NAME

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

14.3 TRANSPORT HAZARD CLASS(ES)

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

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14.4 PACKING GROUP

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

14.5 ENVIRONMENTAL HAZARDS

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

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 should not be considered hazardous 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:



Irritant

Risk phrases:

R36/38 Irritating to eyes and skin.

Safety phrases:

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S27 Take off immediately all contaminated clothing.

S28 After contact with skin, wash immediately with plenty of water.

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

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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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