

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

AZELAIC ACID

1. Identification of the substance/mixture and company

Trade name: Azelaic acid
I.N.C.I. Azelaic acid
CAS No. : 123-99-9
EINESCS No. : 204-669-1
REACH pre-registration No. : 01-2119557891-28-0000
Utilization: Raw material for cosmetic or professional use
Supplier company identification: Elemental SRL, Piața Cazărmii no.15, 410188-Oradea, jud.Bihor, Romania
Tel/Fax: +40259-436.755, www.elemental.eu
Emergency: RO: număr național pentru cazuri de urgență: 021 3183606
Institutul de Sănătate Publică București.
International emergency number: +49 180 2273-112

2. Hazards Identification

2.1 Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Eye irritation, category 2 Causes serious eye irritation. H319 Skin irritation, category 2 Causes skin irritation. H315

2.2. Label elements Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms



Signal words: Warning

Hazard statements:

H319 Causes serious eye irritation.

H315 Causes skin irritation. Precautionary statements:

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.

P332+P313 If skin irritation occurs: Get medical advice / attention.

P337+P313 If eye irritation persists: Get medical advice / attention.

P362+P364 Take off contaminated clothing and wash it before reuse

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%

3. Declaration of ingredients

3.1. Substances

Contains:

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| | | |
|--|---------|---|
| Identification | Conc. % | Classification 1272/2008 (CLP) |
| AZELAIC ACID CAS123-99-9 | 100 | Eye Irrit. 2 H319, Skin Irrit. 2 H315EC204-669-1INDEX |
| Reg. no.01-2119557891-28-0000 | | |
| The full wording of hazard (H) phrases is given in section 16 of the sheet | | |

4. First aid measures

4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

4.2. Most important symptoms and effects, both acute and delayed Information not available**4.3. Indication of any immediate medical attention and special treatment needed** Information not available**5. Fire fighting measures**

5.1 Means of extinction

SUITABLE EXTINGUISHING EQUIPMENT The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT None in particular

5.2 Special hazards arising from the substance or mixture

Exposure to decomposition products may be a hazard to health

5.3 Recommendations for fire-fighters

GENERAL INFORMATION Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137)

5.4 Further information

Evacuate personnel to safe areas. Evacuate personnel and keep upwind of fire.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

If there are no contraindications, spray powder with water to prevent the formation of dust. Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to

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prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues. Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.6.4. Reference to other sections Any information on personal protection and disposal is given in sections 8 and 13..

7. Handling and storage

7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight, below 50°C. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

See the exposure scenarios attached to this safety data sheet.

8. Exposure controls / personal protection

8.1 Control parameters

Predicted no-effect concentration - PNEC

Normal value in fresh water 0,02mg/l

Normal value in marine water 0,002mg/l

Normal value for fresh water sediment 0,0931mg/kg

Normal value for marine water sediment 0,00931mg/kg

Normal value for water, intermittent release 0,16mg/l

Normal value of STP microorganisms 912mg/l

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert particulate not otherwise classified (PNOC respirable fraction: 3 mg/m³; PNOC inhalable fraction: 10 mg/m³). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration. When choosing personal protective equipment, ask your chemical substance supplier for advice. Personal protective equipment must be CE marked, showing that it complies with applicable standards. When choosing risk management measures and operating conditions, consult the exposure scenarios attached. Provide an emergency shower with face and eye wash station.

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HAND PROTECTION In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374). Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

SKIN PROTECTION Wear category II professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION Use a type P filtering facemask, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment (see standard EN 149).

ENVIRONMENTAL EXPOSURE CONTROLS The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards. For information on controlling environmental exposure, see the exposure scenarios attached to this safety datasheet.

9. Physical and chemical properties

9.1 Information on physical and chemical properties

Appearance: solid

Colour: white

Odour: characteristic

Odour threshold: Not available

pH: Not available

Melting point / freezing point: 106°C

Initial boiling point: 357°C

Boiling range: Not available

Flash point: 180°C

Evaporation Rate: Not available

Flammability of solids and gases: Not available

Lower inflammability limit: Not available

Upper inflammability limit: Not available

Lower explosive limit: Not available

Upper explosive limit: Not available

Vapour pressure: Not available

Vapour density: Not available

Relative density: 0,50-0,60

Solubility: 2,4 g/l in water

Partition coefficient: n-octanol/water: 1,57

Auto-ignition temperature: Not available

Decomposition temperature: Not available

Viscosity: Not available

Explosive properties: Not available

Oxidising properties: Not available

9.2 Other information

Total solids (250°C / 482°F): 100,00 %

10. Stability and reactivity

10.1. Reactivity

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There are no particular risks of reaction with other substances in normal conditions of use. Reacts with: strong acids, bases, strong oxidising agents.

10.2. Chemical stability

The product is stable in normal conditions of use and storage. Stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

The powders are potentially explosive when mixed with air. Stable in normal conditions of use and storage.

10.4. Conditions to avoid

Avoid environmental dust build-up. Avoid exposure to: heat, ignition sources, naked flames.

10.5. Incompatible materials

Avoid contact with: strong acids, bases, strong oxidising agents.

10.6. Hazardous decomposition products

When heated to decomposition releases: carbon oxides.

11. Toxicological information

11.1 Information on toxicological effects

Primary routes of exposure

Routes of entry for solids and liquids are ingestion and inhalation, but may include eye or skin contact. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.

Acute Toxicity/Effects

Acute toxicity

Assessment of acute toxicity: Virtually nontoxic after a single ingestion. The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Oral

Type of value: LD50

Species: rat

Value: > 2,000 mg/kg (BASF-Test)

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Inhalation

No applicable information available.

Dermal

No applicable information available.

Type of value: ATE

Value: > 5,000 mg/kg

Assessment other acute effects

No applicable information available.

Irritation / corrosion

Assessment of irritating effects: Not irritating to the skin. Eye contact causes irritation. The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Skin

Species: rabbit

Result: non-irritant

Method: OECD Guideline 404

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Eye

Species: rabbit

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Result: Irritant.

Method: OECD Guideline 405

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Sensitization

Assessment of sensitization: No applicable information available.

Guinea pig maximization test

Species: guinea pig

Result: Non-sensitizing.

Method: OECD Guideline 406

Aspiration Hazard

No data available.

Chronic Toxicity/Effects

Repeated dose toxicity

Assessment of repeated dose toxicity: No applicable information available.

Genetic toxicity

Assessment of mutagenicity: The substance was not mutagenic in bacteria. The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Carcinogenicity

Assessment of carcinogenicity: No data was available concerning carcinogenic activity.

Reproductive toxicity

Assessment of reproduction toxicity: No data available.

Teratogenicity

Assessment of teratogenicity: No data available.

Symptoms of Exposure

Eye irritation

12. Ecological information

12. Ecological Information

Toxicity

Aquatic toxicity

Assessment of aquatic toxicity:

There is a high probability that the product is not acutely harmful to aquatic organisms.

Toxicity to fish

LC50 (48 h) 310 mg/l, *Leuciscus idus* (OECD 203; ISO 7346; 84/449/EEC, C.1, static)

The details of the toxic effect relate to the nominal concentration.

Aquatic invertebrates

EC50 (24 h) 70 mg/l, *Daphnia magna* (OECD Guideline 202, part 1, static)

The details of the toxic effect relate to the nominal concentration.

Aquatic plants

EC50 (24 h) > 10 mg/l (growth rate), *Desmodemus subspicatus* (OECD Guideline 201)

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Analogous: Assessment derived from products with similar chemical character.

No observed effect concentration (24 h) > 10 mg/l (growth rate), *Desmodemus subspicatus* (OECD Guideline 201)

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Analogous: Assessment derived from products with similar chemical character.

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Chronic toxicity to fish

No data available regarding toxicity to fish.

Chronic toxicity to aquatic invertebrates

No data available regarding toxicity to daphnids.

Microorganisms/Effect on activated sludge

Toxicity to microorganisms

No data available.

Persistence and degradability

Assessment biodegradation and elimination (H₂O)

Product is expected to be readily biodegradable.

Elimination information 79 - 89 % DOC reduction (19 d) (OECD 301E/92/69/EEC, C.4-B) (aerobic) Readily biodegradable (according to OECD criteria).

100 % CO₂ formation relative to the theoretical value (18 d) (OECD 301D; EEC 92/69, C.4-E) (aerobic) Readily biodegradable (according to OECD criteria).

Bioaccumulative potential

Because of the n-octanol/water distribution coefficient (log Pow) accumulation in organisms is not to be expected.

Mobility in soil Assessment transport between environmental compartments: not determined

13. Disposal considerations

13.1 Waste treatment methods

Waste disposal of substance:

Dispose of in accordance with national, state and local regulations.

Container disposal:

Dispose of in accordance with national, state and local regulations

14. Transport information

Land transport

USDOT: Not classified as a dangerous good under transport regulations

Sea transport

IMDG: Not classified as a dangerous good under transport regulations

Air transport

IATA/ICAO: Not classified as a dangerous good under transport regulations.

Special precautions for user: Not applicable

Transport in bulk according to Annex II of Marpol and the IBC Code: Information not relevant

15. Regulatory information

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

None

Seveso Category - Directive 2012/18/EC: none

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006: None

Substances in Candidate List (Art. 59 REACH): On the basis of available data, the product does not contain any SVHC in percentage \geq than 0,1%.

Substances subject to authorisation (Annex XIV REACH): None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None

Substances subject to the Rotterdam Convention: None

Substances subject to the Stockholm Convention: None

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Healthcare controls: Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment A chemical safety assessment has been performed for the substance

16. Additional information

16.1 Abbreviations:

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS: Chemical Abstracts Service (division of the American Chemical Society).
CLP: Classification, Labeling, Packaging.
DNEL: Derived No Effect Level.
EINECS: European Inventory of Existing Commercial Chemical Substances.
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.
IATA: International Air Transport Association.
IATA-DGR: Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO: International Civil Aviation Organization.
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG: International Maritime Code for Dangerous Goods.
INCI: International Nomenclature of Cosmetic Ingredients.
LTE: Long-term exposure.
PNEC: Predicted No Effect Concentration.
RID: Regulation Concerning the International Transport of Dangerous Goods by Rail.
STE: Short-term exposure.
STEL: Short Term Exposure limit.
STOT: Specific Target Organ Toxicity.
TLV: Threshold Limit Value
TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
TWA STEL: Short-term exposure limit
TWA: Time-weighted average exposure limit
VOC: Volatile organic Compounds
vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
WGK: Water hazard classes (German)

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Eye Irrit. 2 Eye irritation, category 2

Skin Irrit. 2 Skin irritation, category 2

H319 Causes serious eye irritation. H315 Causes skin irritation.

Disclaimer:

This material safety data sheet does not constitute a guarantee of the properties of the product and is not a contractual legal report. The information is given in good faith on the basis of our best knowledge of the product at the indicated time. However, we cannot accept responsibility or liability for any consequences arising from its use, no warranty for correctness and completeness is given. We caution the users against the incurred possible risks when the product is used at other ends than the use for which it was initially planned. It is the user's responsibility during handling, storage and product use to consult the main regulatory texts in force regarding workers and environment protection.