

AZELAIC ACID

Version number: GHS 2.0
Replaces version of: 2016-03-10 (GHS 1)

Revision: 2017-07-18

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Identification of the substance	Azelaic acid
1.1.2 Trade name	Azepur 99
Registration number (REACH)	01-2119557891-28-xxxx
EC number	204-669-1
CAS number	123-99-9

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Cosmetics Pharmaceuticals Skin lightening, anti acne, treatment rosacea and haircare
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1.3 Details of the supplier of the safety data sheet

Azelaic Products BV
Mussenberg 1
6049 GR Roermond

Telephone: +31475782540
e-mail: info@azelaic.com
Website: www.azelaic.com

e-mail (competent person) info@azelaic.com

1.4 Emergency telephone number

Poison centre		
Country	Name	Telephone
United Kingdom	National Poisons Information Service (NPIS) (medical professionals only)	0344-8920111

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Category	Hazard class and category	Hazard statement
3.2	skin corrosion/irritation	2	Skin Irrit. 2	H315
3.3	serious eye damage/eye irritation	2	Eye Irrit. 2	H319

For full text of abbreviations: see SECTION 16.

2.2 Label elements

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

- signal word warning

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- pictograms

GHS07



- hazard statements

H315 Causes skin irritation.
H319 Causes serious eye 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

According to the results of its assessment, this substance is not a PBT or a vPvB. Dust explosion hazards.

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance	Azelaic acid
Identifiers	
REACH Reg. No	01-2119557891-28-xxxx
CAS No	123-99-9
EC No	204-669-1
Molecular formula	C9H16O4
Molar mass	188.2 g/mol

Remarks

Our azelaic acid is 100% based on vegetable oil (Sunflower oil or distel oil/ cardiano mariano).

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

Provide fresh air. If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician.

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Following skin contact

Brush off loose particles from skin. Rinse skin with water/shower.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious).

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

For specialist advice physicians should contact the anti poison control centre.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water; Foam; Alcohol resistant foam; Dry extinguishing powder; ABC-powder; Foam

Unsuitable extinguishing media

Water jet.

5.2 Special hazards arising from the substance or mixture

Deposited combustible dust has considerable explosion potential.

Hazardous combustion products

During fire hazardous fumes/smoke could be produced.

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

Special protective equipment for firefighters

Self-contained breathing apparatus (EN 133). Standard protective clothing for firefighters.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety. Ventilate affected area. Control of dust.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases. Use personal protective equipment as required.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advices on how to contain a spill

Covering of drains. Take up mechanically.

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Advices on how to clean up a spill

Take up mechanically. Control of dust. Only vacuum cleaners containing no ignition sources may be used for combustible dusts.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Take precautionary measures against static discharge. Use only in well-ventilated areas. Ground/bond container and receiving equipment.

- specific notes/details

Dust deposits may accumulate on all deposition surfaces in a technical room. The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- explosive atmospheres

Removal of dust deposits.

- flammability hazards

Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge.

- incompatible substances or mixtures

Observe hints for combined storage. Keep away from alkalis, oxidising substances, acids.

Control of effects

Protect against external exposure, such as

High temperatures. UV-radiation/sunlight.

Consideration of other advice

Store in a well-ventilated place. Keep container tightly closed.

- ventilation requirements

Use local and general ventilation.

7.3 Specific end use(s)

There is no additional information.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)									
Country	Name of agent	CAS No	Notation	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Source
GB	dust		i	WEL		10			EH40/2005
GB	dust		r	WEL		4			EH40/2005

Notation

i inhalable fraction
r respirable fraction
STEL short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified
TWA time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average

Relevant DNELs/DMELs/PNECs and other threshold levels

Relevant DNELs and other threshold levels				
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
DNEL	17.63 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
DNEL	10 mg/kg	human, dermal	worker (industry)	chronic - systemic effects
DNEL	4.348 mg/m ³	human, inhalatory	consumer (private households)	chronic - systemic effects
DNEL	5 mg/kg	human, dermal	consumer (private households)	chronic - systemic effects
DNEL	2.5 mg/kg	human, oral	consumer (private households)	chronic - systemic effects

Relevant PNECs and other threshold levels				
Endpoint	Threshold level	Organism	Environmental compartment	Exposure time
PNEC	0.02 mg/l	aquatic organisms	freshwater	short-term (single instance)
PNEC	0.002 mg/l	aquatic organisms	marine water	short-term (single instance)
PNEC	0.16 mg/l	aquatic organisms	water	intermittent release
PNEC	912 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
PNEC	0.093 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
PNEC	0.009 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
PNEC	0.007 mg/kg	terrestrial organisms	soil	short-term (single instance)

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8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection (EN 166).

Skin protection

Protective clothing (EN 340).

- hand protection



Chemical protection gloves are suitable, which are tested according to EN 374. 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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

Control of dust. Avoid inhalation of the product. In case of inadequate ventilation wear respiratory protection. P2 (filters at least 94 % of airborne particles, colour code: White).

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state	solid (powder, flakes)
Colour	white
Odour	characteristic

Other safety parameters

pH (value)	not applicable
Melting point/freezing point	106.5 °C
Initial boiling point and boiling range	357.1 °C
Flash point	180 °C
Evaporation rate	not determined
Flammability (solid, gas)	this material is combustible, but will not ignite readily
Explosion limits of dust clouds	not determined
Vapour pressure	not determined

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Density	1,225 kg/m ³ at 25 °C
Vapour density	this information is not available
Solubility(ies)	
- water solubility	1 g/l at 1 °C
Partition coefficient	
- n-octanol/water (log KOW)	1.57 (ECHA)
Auto-ignition temperature	not determined
Viscosity	not relevant (solid matter)
Explosive properties	none
Oxidising properties	none

9.2 Other information

Of no significance.

Surface tension	41.6 mN/m (23 °C) (ECHA)
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SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

Keep away from heat.

Hints to prevent fire or explosion

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

10.5 Incompatible materials

Oxidisers.

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Shall not be classified as acutely toxic.

GHS of the United Nations, annex 4: May be harmful in contact with skin.

Acute toxicity			
Exposure route	Endpoint	Value	Species
oral	LD50	15,800 mg/kg	rat
inhalation: vapour	LC50	>0.162 mg/l/4h	rat
dermal	LD50	>2,000 mg/kg	rabbit

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

The classification criteria for this hazard class are not met. Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

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SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute)			
Endpoint	Value	Species	Exposure time
LC50	>16 mg/l	fish	96 h
EC50	>20 mg/l	aquatic invertebrates	48 h
ErC50	>100 mg/l	algae	72 h

Aquatic toxicity (chronic)			
Endpoint	Value	Species	Exposure time
LC50	9.8 mg/l	fish	28 d
EC50	0.51 mg/l	aquatic invertebrates	21 d

12.2 Persistence and degradability

Process of degradability		
Process	Degradation rate	Time
oxygen depletion	86 %	30 d

12.3 Bioaccumulative potential

n-octanol/water (log KOW)	1.57 (ECHA)
BCF	249

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

12.6 Other adverse effects

Data are not available.

Endocrine disrupting potential

Not listed.

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment.

Waste treatment of containers/packageings

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

- | | |
|--------------------------------------------------------------------------------|-----------------------------------------------------------------------|
| 14.1 UN number | not subject to transport regulations |
| 14.2 UN proper shipping name | not relevant |
| 14.3 Transport hazard class(es) | |
| Class | - |
| 14.4 Packing group | not relevant |
| 14.5 Environmental hazards | non-environmentally hazardous acc. to the dangerous goods regulations |
| 14.6 Special precautions for user | |
| There is no additional information. | |
| 14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code | |
| No data available. | |

Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN)

Not subject to ADR, RID and ADN.

International Maritime Dangerous Goods Code (IMDG)

Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR)

Not subject to ICAO-IATA.

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- Relevant provisions of the European Union (EU)**
- Restrictions according to REACH, Annex XVII**
- Not listed.

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List of substances subject to authorisation (REACH, Annex XIV)

Not listed.

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) - Annex II

not listed

Regulation 166/2006/EC concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

Not listed.

Directive 2000/60/EC establishing a framework for Community action in the field of water policy (WFD)

Not listed.

Regulation 98/2013/EU on the marketing and use of explosives precursors

Not listed.

15.2 Chemical Safety Assessment

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

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
2.1	Additional information: According to the results of its assessment, this substance is not a PBT or a vPvB.		yes
4.1	Following inhalation: If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician. Provide fresh air.	Following inhalation: Provide fresh air. If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician.	yes
4.1	Following eye contact: Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.	Following eye contact: Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart.	yes
5.1	Suitable extinguishing media: Water, Foam, Alcohol resistant foam, ABC-powder	Suitable extinguishing media: Water; Foam; Alcohol resistant foam; Dry extinguishing powder; ABC-powder; Foam	yes
5.2	Hazardous combustion products: Carbon monoxide (CO), Carbon dioxide (CO ₂), During fire hazardous fumes/smoke could be produced	Hazardous combustion products: During fire hazardous fumes/smoke could be produced.	yes
6.1	For non-emergency personnel: Remove persons to safety. Ventilate affected area. Control of dust. Keep away from sources of ignition - No smoking.	For non-emergency personnel: Remove persons to safety. Ventilate affected area. Control of dust.	yes
6.1	For emergency responders: Wear breathing apparatus if exposed to vapours/dust/spray/gases.	For emergency responders: Wear breathing apparatus if exposed to vapours/dust/spray/gases. Use personal protective equipment as required.	yes
7.2	Protect against external exposure, such as: High temperatures, UV-radiation/sunlight, Static discharges	Protect against external exposure, such as: High temperatures. UV-radiation/sunlight.	yes
8.1		Occupational exposure limit values (Workplace Exposure Limits): change in the listing (table)	yes

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Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
8.2	Eye/face protection: eye protection must be worn Use safety goggle with side protection.	Eye/face protection: eye protection must be worn Use safety goggle with side protection (EN 166).	yes
8.2	Skin protection	Skin protection: Protective clothing (EN 340).	yes
8.2	Hand protection: safety gloves must be worn Chemical protection gloves are suitable, which are tested according to EN 374.	Hand protection: safety gloves must be worn Chemical protection gloves are suitable, which are tested according to EN 374. 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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.	yes
9.2	Other information	Other information: Of no significance.	yes
9.2	Solid content: 100 %		yes
10.4	Conditions to avoid: There are no specific conditions known which have to be avoided.	Conditions to avoid: Keep away from heat.	yes
11.1	Acute toxicity: Shall not be classified as acutely toxic.	Acute toxicity: Shall not be classified as acutely toxic. GHS of the United Nations, annex 4: May be harmful in contact with skin.	yes
11.1	Specific target organ toxicity - repeated exposure: Shall not be classified as a specific target organ toxicant (repeated exposure).	Specific target organ toxicity - repeated exposure: The classification criteria for this hazard class are not met. Shall not be classified as a specific target organ toxicant (repeated exposure).	yes
13.1	Sewage disposal-relevant information: Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.	Sewage disposal-relevant information: Do not empty into drains. Avoid release to the environment.	yes
14.5	Environmental hazards	Environmental hazards: non-environmentally hazardous acc. to the dangerous goods regulations	yes
14.7	Transport in bulk according to Annex II of MARPOL and the IBC Code: The cargo is not intended to be carried in bulk.	Transport in bulk according to Annex II of MARPOL and the IBC Code: No data available.	yes
15.2	Chemical Safety Assessment: No Chemical Safety Assessment has been carried out for this substance.	Chemical Safety Assessment: No Chemical Safety Assessment has been carried out for this substance by the supplier.	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
BCF	Bioconcentration factor
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)

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Abbr.	Descriptions of used abbreviations
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-licence/)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
MARPOL	International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant")
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
STEL	Short-term exposure limit
TWA	Time-weighted average
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2015/830/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

List of relevant phrases (code and full text as stated in chapter 2 and 3)

Code	Text
H315	Causes skin irritation.
H319	Causes serious eye irritation.

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Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.