



Aelite LS Posterior

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Revision date: 12/19/2024 Supersedes version of: 1/9/2023 Version: 4.0

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

1.1. Product identifier

Product form : Mixture
Product name : Aelite LS Posterior

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

Relevant identified uses

Use of the substance/mixture : For Rx Only

1.3. Details of the supplier of the safety data sheet

Manufacturer

BISCO, Inc.
1100 W. Irving Park Rd.
60193 Schaumburg, IL
U.S.A
T 1-800-247-3368 or 1-847-534-6000
sales@bisco.com - www.bisco.com

EC REP

BISICO France
208, allée de la Coudoulette
13680 Lançon de Provence
France
T 33-4-90-42-92-92

1.4. Emergency telephone number

Emergency number : CHEMTREC - 24-Hour Hazmat Emergency Communications Center
Domestic: 1-800-424-9300 Outside the U.S.: 1-703-527-3887, collect calls accepted

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1 H317
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : Warning
Contains : Triethylene Glycol Dimethacrylate; BisGMA
Hazard statements (CLP) : H317 - May cause an allergic skin reaction.
Precautionary statements (CLP) : P261 - Avoid breathing dust, fume, vapours.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, eye protection.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation, a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste.

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2.3. Other hazards

Contains no PBT and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

| Component | |
|---|---|
| Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII | Ethoxylated Bis A Dimethacrylate (41637-38-1), Triethylene Glycol Dimethacrylate (109-16-0) |
| Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII | Ethoxylated Bis A Dimethacrylate (41637-38-1), Triethylene Glycol Dimethacrylate (109-16-0) |

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.2. Mixtures

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|-----------------------------------|---|---------|--|
| Silicon Dioxide | CAS-No.: 112945-52-5 | 10 - 30 | Not classified |
| Ethoxylated Bis A Dimethacrylate | CAS-No.: 41637-38-1 | 5 - 10 | Aquatic Chronic 4, H413 |
| Triethylene Glycol Dimethacrylate | CAS-No.: 109-16-0 EC-No.: 203-652-6 | 1 - 5 | Skin Sens. 1B, H317 |
| BisGMA | CAS-No.: 1565-94-2 EC-No.: 216-367-7 | < 1 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335 |

Full text of H- and EUH-statements: see section 16

Components - Nanoform

| Silicon Dioxide (112945-52-5) | |
|---|-----------------|
| Name of (set of) nanoform(s) | Silicon Dioxide |
| Number based particle size distribution | 40 nm |
| Particle shape | Crystal |
| Specific surface area | 50 m2/g |

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|--|
| First-aid measures after inhalation | : Remove person to fresh air and keep comfortable for breathing. |
| First-aid measures after skin contact | : Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention. |
| First-aid measures after eye contact | : Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. |
| First-aid measures after ingestion | : Call a poison center or a doctor if you feel unwell. |

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

| | |
|-------------------------------------|--|
| Symptoms/effects after skin contact | : May cause an allergic skin reaction. |
| Symptoms/effects after eye contact | : May cause eye irritation. |

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust, fume, vapours.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Mechanically recover the product.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing dust, fume, vapours. Wear personal protective equipment.
Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protection equipment

Personal protective equipment symbol(s):



Eye and face protection

Eye protection:

Safety glasses

Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|------------------|
| Physical state | : Solid |
| Colour | : Tooth. |
| Appearance | : Paste. |
| Odour | : Acrylic. |
| Odour threshold | : Not available |
| Melting point | : Not available |
| Freezing point | : Not applicable |
| Boiling point | : Not available |
| Flammability | : Non flammable. |
| Lower explosion limit | : Not applicable |
| Upper explosion limit | : Not applicable |
| Flash point | : Not applicable |
| Auto-ignition temperature | : Not applicable |
| Decomposition temperature | : Not available |
| pH | : Not available |
| pH solution | : Not available |
| Viscosity, kinematic | : Not applicable |
| Solubility | : Not available |
| Partition coefficient n-octanol/water (Log Kow) | : Not available |
| Vapour pressure | : Not available |

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| | |
|---------------------------------|------------------|
| Vapour pressure at 50°C | : Not available |
| Density | : Not available |
| Relative density | : Not applicable |
| Relative vapour density at 20°C | : Not applicable |
| Particle size | : Not available |

See section 3 for more information about nano properties.

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

| | |
|-----------------------------|------------------|
| Acute toxicity (oral) | : Not classified |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |

| Ethoxylated Bis A Dimethacrylate (41637-38-1) | |
|---|---|
| LD50 oral rat | > 2000 mg/kg Source: ECHA |
| LD50 dermal rat | > 2000 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Read-across, Dermal, 15 day(s)) |
| Triethylene Glycol Dimethacrylate (109-16-0) | |
| LD50 oral rat | 10837 mg/kg Source: NLM, THOMSON |
| LD50 dermal | > 2000 mg/kg bodyweight (US EPA, 14 day(s), Mouse, Male, Experimental value, Skin, 14 day(s)) |
| Silicon Dioxide (112945-52-5) | |
| LD50 oral rat | > 5000 mg/kg (Rat, Literature study, Oral) |
| LD50 dermal rabbit | > 5000 mg/kg (Rabbit, Literature study, Dermal) |

| | |
|---------------------------|------------------|
| Skin corrosion/irritation | : Not classified |
|---------------------------|------------------|

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| | |
|--|--|
| Ethoxylated Bis A Dimethacrylate (41637-38-1) | |
| pH | 4.7 (< 0.01 %, 20 °C, OECD 105: Water Solubility) |
| Triethylene Glycol Dimethacrylate (109-16-0) | |
| pH | 6.8 - 7.2 |
| Silicon Dioxide (112945-52-5) | |
| pH | 3.6 - 4.5 (4 %) |
| Serious eye damage/irritation | : Not classified |
| Ethoxylated Bis A Dimethacrylate (41637-38-1) | |
| pH | 4.7 (< 0.01 %, 20 °C, OECD 105: Water Solubility) |
| Triethylene Glycol Dimethacrylate (109-16-0) | |
| pH | 6.8 - 7.2 |
| Silicon Dioxide (112945-52-5) | |
| pH | 3.6 - 4.5 (4 %) |
| Respiratory or skin sensitisation | : May cause an allergic skin reaction. |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |
| BisGMA (1565-94-2) | |
| STOT-single exposure | May cause respiratory irritation. |
| STOT-repeated exposure | : Not classified |
| Triethylene Glycol Dimethacrylate (109-16-0) | |
| LOAEC (inhalation, rat, gas, 90 days) | 350 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Remarks on results: other: |
| NOAEL (oral, rat, 90 days) | 1000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test) |
| NOAEC (inhalation, rat, gas, 90 days) | 100 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Remarks on results: other: |
| Aspiration hazard | : Not classified |
| Aelite LS Posterior | |
| Viscosity, kinematic | Not applicable |
| Ethoxylated Bis A Dimethacrylate (41637-38-1) | |
| Viscosity, kinematic | No data available in the literature |
| Silicon Dioxide (112945-52-5) | |
| Viscosity, kinematic | Not applicable |

11.2. Information on other hazards

No additional information available

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SECTION 12: Ecological information

12.1. Toxicity

| | |
|---|---|
| Ecology - general | : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment. |
| Hazardous to the aquatic environment, short-term (acute) | : Not classified |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified |

Ethoxylated Bis A Dimethacrylate (41637-38-1)

| | |
|----------------------|-------------------------|
| LC50 - Fish [1] | > 100 mg/l Source: ECAH |
| EC50 72h - Algae [1] | > 100 mg/l Source: ECAH |

Triethylene Glycol Dimethacrylate (109-16-0)

| | |
|----------------------|---|
| LC50 - Fish [1] | 16.4 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio) |
| EC50 72h - Algae [1] | > 100 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) |
| EC50 72h - Algae [2] | 72.8 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) |
| ErC50 algae | > 100 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, Nominal concentration) |
| LOEC (chronic) | 100 mg/l Test organisms (species): Daphnia magna Duration: '21 d' |
| NOEC (chronic) | 32 mg/l Test organisms (species): Daphnia magna Duration: '21 d' |

BisGMA (1565-94-2)

| | |
|-----------------|---------------------------|
| LC50 - Fish [1] | 0.537 mg/l Source: ECOSAR |
|-----------------|---------------------------|

12.2. Persistence and degradability

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| | |
|-------------------------------|--------------------|
| Persistence and degradability | Rapidly degradable |
|-------------------------------|--------------------|

Ethoxylated Bis A Dimethacrylate (41637-38-1)

| | |
|-------------------------------|-------------------------------------|
| Persistence and degradability | Not readily biodegradable in water. |
|-------------------------------|-------------------------------------|

Triethylene Glycol Dimethacrylate (109-16-0)

| | |
|-------------------------------|---------------------------------|
| Persistence and degradability | Readily biodegradable in water. |
|-------------------------------|---------------------------------|

Silicon Dioxide (112945-52-5)

| | |
|-------------------------------|-----------------------------------|
| Persistence and degradability | Biodegradability: not applicable. |
| Chemical oxygen demand (COD) | Not applicable |
| ThOD | Not applicable |
| BOD (% of ThOD) | Not applicable |

BisGMA (1565-94-2)

| | |
|-------------------------------|---|
| Persistence and degradability | Biodegradability in water: no data available. |
|-------------------------------|---|

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12.3. Bioaccumulative potential

Ethoxylated Bis A Dimethacrylate (41637-38-1)

| | |
|---|---|
| Partition coefficient n-octanol/water (Log Pow) | 5.62 (Practical experience/observation, OECD 117: Partition Coefficient (n-octanol/water), HPLC method) |
| Bioaccumulative potential | High potential for bioaccumulation (Log Kow > 5). |

Triethylene Glycol Dimethacrylate (109-16-0)

| | |
|---|--|
| Partition coefficient n-octanol/water (Log Pow) | 2.3 (Experimental value, OECD 117: Partition Coefficient (n-octanol/water), HPLC method) |
| Bioaccumulative potential | Low potential for bioaccumulation (Log Kow < 4). |

Silicon Dioxide (112945-52-5)

| | |
|---------------------------|----------------------|
| Bioaccumulative potential | Not bioaccumulative. |
|---------------------------|----------------------|

BisGMA (1565-94-2)

| | |
|---|------------------------------------|
| Partition coefficient n-octanol/water (Log Pow) | 4.94 (Estimated value) |
| Bioaccumulative potential | No bioaccumulation data available. |

12.4. Mobility in soil

Ethoxylated Bis A Dimethacrylate (41637-38-1)

| | |
|--|---|
| Surface tension | No data available in the literature |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 2.56 - 3.88 (log Koc, Calculated value) |
| Ecology - soil | Low potential for mobility in soil. |

Triethylene Glycol Dimethacrylate (109-16-0)

| | |
|--|---|
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 1.89 (log Koc, SRC PCKOCWIN v2.0, Calculated value) |
| Ecology - soil | Highly mobile in soil. |

12.5. Results of PBT and vPvB assessment

Component

| | |
|---|---|
| Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII | Ethoxylated Bis A Dimethacrylate (41637-38-1), Triethylene Glycol Dimethacrylate (109-16-0) |
| Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII | Ethoxylated Bis A Dimethacrylate (41637-38-1), Triethylene Glycol Dimethacrylate (109-16-0) |

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

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SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

14.1. UN number or ID number

Not regulated for transport

14.2. UN proper shipping name

| | |
|-----------------------------|------------------|
| Proper Shipping Name (ADR) | : Not applicable |
| Proper Shipping Name (IMDG) | : Not applicable |
| Proper Shipping Name (IATA) | : Not applicable |
| Proper Shipping Name (ADN) | : Not applicable |
| Proper Shipping Name (RID) | : Not applicable |

14.3. Transport hazard class(es)

ADR
Transport hazard class(es) (ADR) : Not applicable

IMDG
Transport hazard class(es) (IMDG) : Not applicable

IATA
Transport hazard class(es) (IATA) : Not applicable

ADN
Transport hazard class(es) (ADN) : Not applicable

RID
Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

| | |
|----------------------|------------------|
| Packing group (ADR) | : Not applicable |
| Packing group (IMDG) | : Not applicable |
| Packing group (IATA) | : Not applicable |
| Packing group (ADN) | : Not applicable |
| Packing group (RID) | : Not applicable |

14.5. Environmental hazards

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport
No data available

Transport by sea
No data available

Air transport
No data available

Inland waterway transport
No data available

Rail transport
No data available

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes

| Section | Changed item | Comments |
|---------|--|-----------------|
| | Revision date | Modified |
| | Supersedes version of | Modified |
| 3 | Composition/information on ingredients | Modified |
| 4.1 | First-aid measures after eye contact | Modified |
| 4.2 | Symptoms/effects after eye contact | Added |

Full text of H- and EUH-statements:

| | |
|-------------------|---|
| Aquatic Chronic 4 | Hazardous to the aquatic environment - Chronic Hazard, Category 4 |
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation. |
| H335 | May cause respiratory irritation. |

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| Full text of H- and EUH-statements: | |
|-------------------------------------|--|
| H413 | May cause long lasting harmful effects to aquatic life. |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| Skin Sens. 1 | Skin sensitisation, Category 1 |
| Skin Sens. 1B | Skin sensitisation, category 1B |
| STOT SE 3 | Specific target organ toxicity - Single exposure, Category 3, Respiratory tract irritation |

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.