

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Revision date: 1/9/2023 Supersedes version of: 7/16/2018 Version: 3.0

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 1.2.1. Relevant identified uses Use of the substance/mixture : For Rx Only 1.2.2. Uses advised against No additional information available 1.3. Details of the supplier of the safety data sheet Manufacturer EC REP BISCO, Inc. **BISICO France** 1100 W. Irving Park Rd. 208, allée de la Coudoulette Schaumburg, IL 60193 13680 Lançon de Provence U.S.A. France T 1-800-247-3368 or 1-847-534-6000 T 33-4-90-42-92-92 www.bisco.com 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

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hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

Component	
Ethoxylated Bis A Dimethacrylate (41637-38-1)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
Triethylene Glycol Dimethacrylate (109-16-0)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

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 is 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

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
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

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	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.
4.2. Most important symptoms and ef	ffects, both acute and delayed
Symptoms/effects after skin contact	: May cause an allergic skin reaction.
4.3. Indication of any immediate med	ical attention and special treatment needed

Treat symptomatically.

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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 equipr	nent and emergency procedures	
6.1.1. For non-emergency personnel Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust, fume, vapours.	
6.1.2. 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 a	and cleaning up	
Methods for cleaning up Other information	Mechanically recover the product.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 stor	age
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, in	ncluding any incompatibilities
Storage conditions	: Store in a well-ventilated place. Keep cool.
7.3. Specific end use(s)	

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

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8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection: Safety glasses

8.2.2.2. Skin protection

Skin and body protection: Wear suitable protective clothing

Hand protection: Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. 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. : Acrylic. Odour Odour threshold : Not available Melting point : Not available : Not applicable Freezing point Boiling point : Not available Flammability : Non flammable. Explosive limits : Not applicable Lower explosion limit : Not applicable

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Upper explosion limit Flash point Auto-ignition temperature Decomposition temperature pH pH solution Viscosity, kinematic Solubility Partition coefficient n-octanol/water (Log Kow) Vapour pressure Vapour pressure at 50°C	 Not applicable Not applicable Not applicable Not available Not available Not available Not available Not applicable Not available
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
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

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) Acute toxicity (dermal) Acute toxicity (inhalation) Not classifiedNot classifiedNot classified

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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
Skin corrosion/irritation :	Not classified
Ethoxylated Bis A Dimethacrylate (41637-38-1	l)
рН	4.7 (0.0002 %, 20 °C, OECD 105: Water Solubility)
Triethylene Glycol Dimethacrylate (109-16-0)	
рН	6.8 - 7.2
Serious eye damage/irritation :	Not classified
Ethoxylated Bis A Dimethacrylate (41637-38-1	1)
рН	4.7 (0.0002 %, 20 °C, OECD 105: Water Solubility)
Triethylene Glycol Dimethacrylate (109-16-0)	
рН	6.8 - 7.2
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)	1
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
11.2. Information on other hazards	

No additional information available

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SECTION 12: Ecological information	
12.1. Toxicity	
Hazardous to the aquatic environment, short-term : (acute)	The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment. Not classified 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 (Equivalent or similar to EU Method C.3, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value)
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'
12.2. Persistence and degradability	
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.
BisGMA (1565-94-2)	
Persistence and degradability	Biodegradability in water: no data available.

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 (Practical experience/observation, EU Method A.8: Partition Coefficient)	
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).	
BisGMA (1565-94-2)		
Partition coefficient n-octanol/water (Log Pow)	4.94 (Estimated value)	
Bioaccumulative potential	No bioaccumulation data available.	

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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, Calculated value)	
Ecology - soil	Highly mobile in soil.	
12.5. Results of PBT and vPvB assessment		
No additional information available		
12.6. Endocrine disrupting properties		

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerat	ions
13.1. Waste treatment methods	
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

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

14.1. UN number or ID number	
UN-No. (ADR) UN-No. (IMDG) UN-No. (IATA) UN-No. (ADN) UN-No. (RID)	 Not applicable Not applicable Not applicable Not applicable Not applicable
14.2. UN proper shipping name	
Proper Shipping Name (ADR) Proper Shipping Name (IMDG) Proper Shipping Name (IATA) Proper Shipping Name (ADN) Proper Shipping Name (RID)	 Not applicable Not applicable Not applicable Not applicable 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

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ADN Transport hazard class(es) (ADN)	: Not applicable	
RID Transport hazard class(es) (RID)	: Not applicable	
14.4. Packing group		
Packing group (ADR) Packing group (IMDG) Packing group (IATA) Packing group (ADN) Packing group (RID)	 Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable 	
14.5. Environmental hazards		
Dangerous for the environment Marine pollutant Other information	: No : No : 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		
SECTION 15: Regulatory information		
15.1. Safety, health and environmental re	egulations/legislation specific for the substance or mixture	
15.1.1. 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 Anne.	x 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)

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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)

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)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes Section Changed item Change Comments Supersedes version of Added Added Image: Composition of the section of th

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.
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.