

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Revision date: 1/6/2023 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 : Aeliteflo LV

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

ManufacturerEC REPBISCO, Inc.BISICO France

1100 W. Irving Park Rd.

Schaumburg, IL 60193

208, allée de la Coudoulette
13680 Lançon de Provence
USA

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 corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319
Skin sensitisation, Category 1 H317

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

Adverse physicochemical, human health and environmental effects

No additional information available

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) : H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation.

Precautionary statements (CLP) : P261 - Avoid breathing dust, fume, vapours.

P264 - Wash hands thoroughly after handling.

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.

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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 supplemental first aid instruction on this label).

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

P333+P313 - If skin irritation or rash 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.

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.

2.3. Other hazards

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

Component	
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
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

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]
Triethylene Glycol Dimethacrylate	CAS-No.: 109-16-0 EC-No.: 203-652-6	10 - 30	Skin Sens. 1B, H317
BisGMA	CAS-No.: 1565-94-2 EC-No.: 216-367-7	5 - 10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335
Ethoxylated Bis A Dimethacrylate	CAS-No.: 41637-38-1	5 - 10	Aquatic Chronic 4, H413
Polybutanediol Dimethacrylate 600	CAS-No.: 28883-57-0	1 - 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Ytterbium Fluoride	CAS-No.: 13760-80-0 EC-No.: 237-354-2	1 - 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319

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 general

: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

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First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a POISON

CENTER/doctor if you feel unwell.

First-aid measures after skin contact : Wash skin with plenty of water. If skin irritation occurs: Get medical advice/attention.

Specific treatment (see First aid measures on this label). Wash contaminated clothing

before reuse.

First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness

persists.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : Causes skin irritation.

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 : Foam. Dry powder. Carbon dioxide. Unsuitable extinguishing media : Do not use a heavy water stream.

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

Firefighting instructions : Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering

the environment.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Use self-contained

breathing apparatus and chemically protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

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. Notify authorities if liquid enters sewers or public waters.

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.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling

: Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures

Do not eat, drink or smoke when using this product. Always wash hands after handling the

product. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep cool. Protect from sunlight.

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

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:

Avoid all unnecessary exposure.

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

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8.2.2.3. Respiratory protection

Respiratory protection:

Wear appropriate mask

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Colour : Tooth.

Appearance : Flowable paste. Odour : Acrylic. Odour threshold : Not available Melting point : Not available : Not available Freezing point : Not available Boiling point : Non flammable. Flammability : Not applicable **Explosive limits** : Not applicable Lower explosion limit Upper explosion limit : Not applicable Flash point : Not applicable Auto-ignition temperature : Not applicable : Not available Decomposition temperature : 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 Vapour pressure at 50°C : Not available Not available Density : Not available Relative density Relative vapour density at 20°C : Not applicable : Not available Particle size Particle size distribution Not available : Not available Particle shape 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.

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10.2. Chemical stability

Stable under normal conditions of use.

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))		
Polybutanediol Dimethacrylate 600 (28883-57-0)			
LD50 oral rat	14500 mg/kg		
Triethylene Glycol Dimethacrylate (109-16-0)			
LD50 oral rat	10837 mg/kg Source: NLM,THOMSON		
Ytterbium Fluoride (13760-80-0)			
LD50 oral rat	> 2000 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 420 (Acute Oral Toxicity - Fixed Dose Method), Guideline: EU Method B.1 bis (Acute Oral Toxicity - Fixed Dose Procedure)		

Skin corrosion/irritation : Causes skin irritation.

Additional information : Causes skin irritation.

Ethoxylated Bis A Dimethacrylate (41637-38-1)		
pH 4.7 (0.0002 %, 20 °C, OECD 105: Water Solubility)		
Triethylene Glycol Dimethacrylate (109-16-0)		
pH 6.8 - 7.2		
Ytterbium Fluoride (13760-80-0)		
pH 4.53 Temp.: 20 °C		

Serious eye damage/irritation : Causes serious eye irritation.

Ethoxylated Bis A Dimethacrylate (41637-38-1)	
pH 4.7 (0.0002 %, 20 °C, OECD 105: Water Solubility)	

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Triethylene Glycol Dimethacrylate (109-16-0)			
pH	6.8 - 7.2		
Ytterbium Fluoride (13760-80-0)			
рН	4.53 Temp.: 20 °C		
Respiratory or skin sensitisation	: May cause an allergic skin reaction.		
Germ cell mutagenicity	: Not classified		
Carcinogenicity	: Not classified		
Polybutanediol Dimethacrylate 600 (288	83-57-0)		
IARC group	4 - Probably not carcinogenic to humans		
Ytterbium Fluoride (13760-80-0)			
IARC group	4 - Probably not carcinogenic to humans		
Reproductive toxicity	: Not classified		
STOT-single exposure	: Not classified		
Additional information	: May cause respiratory irritation.		
Polybutanediol Dimethacrylate 600 (288	83-57-0)		
STOT-single exposure	May cause respiratory irritation.		
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		
Ethoxylated Bis A Dimethacrylate (41637-38-1)			
Viscosity, kinematic	No data available in the literature		

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

11.2.2. Other information

Potential adverse human health effects and symptoms

: Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

 $\label{thm:local_equation} \mbox{Hazardous to the aquatic environment, short-term}$

(acute)

Hazardous to the aquatic environment, long-term

(chronic)

: Not classified

: Not classified

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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'		
Ytterbium Fluoride (13760-80-0)			
EC50 - Crustacea [1]	> 0.52 mg/l Test organisms (species): Daphnia magna		

12.2. Persistence and degradability

Aeliteflo LV		
Persistence and degradability Not established.		
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

Aeliteflo LV			
Bioaccumulative potential	Not established.		
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	umulative potential Low potential for bioaccumulation (Log Kow < 4).		
Ytterbium Fluoride (13760-80-0)			
Partition coefficient n-octanol/water (Log Pow)	0.22 Source: EPISUITE		
BisGMA (1565-94-2)			
Partition coefficient n-octanol/water (Log Pow) 4.94 (Estimated value)			

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BisGMA (1565-94-2)	
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, 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

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods

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

Product/Packaging disposal recommendations

: Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials

: Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number or ID number

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not regulated
UN-No. (IATA) : Not regulated
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not regulated
Proper Shipping Name (IATA) : Not regulated
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

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IMDG

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

IATA

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

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 regulated
Packing group (IATA) : Not regulated
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/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 Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

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

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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)

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	
	Revision date	Added	
	Issue date	Removed	
2	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
3	Composition/information on ingredients	Modified	

Other information : None.

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.