

Safety Data Sheet

according to UK REACH Regulation

apt flow

Revision date: 09.05.2023

Product code: D300152

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

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

Restorative material intended for the reconstruction or correction of natural dentition.

Uses advised against

None.

1.3. Details of the supplier of the safety data sheet

Company name:	Saremco Dental AG	
Street:	Gewerbestrasse 4	
Place:	CH-9445 Rebstein	
Telephone:	+41 71 775 80 90	Telefax: +41 71 775 80 99
e-mail:	info@saremco.ch	
Contact person:	Dr. Christoph Evers	Telephone: +41 71 775 80 60
e-mail:	Christoph.evers@saremco.ch	
Internet:	www.saremco.ch	
Responsible Department:	Vigilance	

1.4. Emergency telephone number:CH: 145
Ausland: +41 44 251 51 51**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****GB CLP Regulation**Skin Irrit. 2; H315
Eye Irrit. 2; H319
Skin Sens. 1; H317
STOT SE 3; H335

Full text of hazard statements: see SECTION 16.

2.2. Label elements**GB CLP Regulation****Hazard components for labelling**BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE, BisEMA
aromatic urethane methacrylate, NCO monomer resin**Signal word:** Warning**Pictograms:****Hazard statements**H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.**Precautionary statements**

P264 Wash hands thoroughly after handling.

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P280 Wear protective gloves.
 P332+P313 If skin irritation occurs: Get medical advice/attention.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name	Quantity
	EC No	
	Index No	
	REACH No	
	Classification (GB CLP Regulation)	
41637-38-1	BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE, BisEMA	25 - < 50 %
	609-946-4	
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335	
126646-17-1	aromatic urethane methacrylate, NCO monomer resin	5 - < 10 %
	682-529-2	
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335	
128-37-0	Butylated hydroxitoluene	0.1 - < 1 %
	204-881-4	
	Aquatic Chronic 1; H410	

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

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
128-37-0	204-881-4	Butylated hydroxitoluene	0.1 - < 1 %
		oral: LD50 = >6000 mg/kg	

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Rinse mouth immediately and drink 1 glass of water.

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

No information available.

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

Treat symptomatically.

SECTION 5: Firefighting measures

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5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

No special environmental measures are necessary. Clean contaminated articles and floor according to the environmental legislation.

6.3. Methods and material for containment and cleaning up

For cleaning up

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid dust formation. Do not breathe dust.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

Restaurationsmaterial für den Wiederaufbau oder die Korrektur des natürlichen Gebisses.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
128-37-0	2,6-Di-tert-butyl-p-cresol	-	10		TWA (8 h)	WEL

8.2. Exposure controls

Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Individual protection measures, such as personal protective equipment
Eye/face protection

Suitable eye protection: goggles.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties
9.1. Information on basic physical and chemical properties

Physical state:	solid (Paste)	
Colour:	white	
Melting point/freezing point:		not determined
Boiling point or initial boiling point and boiling range:		not determined
Flammability:		not determined
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Flash point:		not applicable
Auto-ignition temperature:		not determined
Decomposition temperature:		not determined
pH-Value:		not determined
Water solubility:	The study does not need to be conducted because the substance is known to be insoluble in water.	
Solubility in other solvents	not determined	
Partition coefficient n-octanol/water:		not determined
Vapour pressure:		not determined
Density:		2.2 g/cm ³
Relative vapour density:		not determined

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9.2. Other information

Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Evaporation rate:

not determined

Solid content:

not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

none

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation

Acute toxicity

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

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
128-37-0	Butylated hydroxitoluene				
	oral	LD50 mg/kg	>6000	rat	OECD 401

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE, BisEMA; aromatic urethane methacrylate, NCO monomer resin)

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

May cause respiratory irritation. (BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE, BisEMA)

STOT-repeated exposure

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

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Aspiration hazard

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

11.2. Information on other hazards**Further information**

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information**12.1. Toxicity**

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

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information**Land transport (ADR/RID)****14.1. UN number or ID number:**

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information**

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Information according to 2012/18/EU (SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D):

-- non-hazardous to water

Skin resorption/Sensitization:

Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

- CLP: Classification, labelling and Packaging
- REACH: Registration, Evaluation and Authorization of Chemicals
- GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
- UN: United Nations
- CAS: Chemical Abstracts Service
- DNEL: Derived No Effect Level
- DMEL: Derived Minimal Effect Level
- PNEC: Predicted No Effect Concentration
- ATE: Acute toxicity estimate
- LC50: Lethal concentration, 50%
- LD50: Lethal dose, 50%
- LL50: Lethal loading, 50%
- EL50: Effect loading, 50%
- EC50: Effective Concentration 50%
- ErC50: Effective Concentration 50%, growth rate
- NOEC: No Observed Effect Concentration
- BCF: Bio-concentration factor
- PBT: persistent, bioaccumulative, toxic
- vPvB: very persistent, very bioaccumulative
- ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
- RID: Regulations concerning the international carriage of dangerous goods by rail
- MARPOL: International Convention for the Prevention of Marine Pollution from Ships
- IBC: Intermediate Bulk Container
- SVHC: Substance of Very High Concern
- @1605.B000001

Classification for mixtures and used evaluation method according to GB CLP Regulation

Classification	Classification procedure
Skin Irrit. 2; H315	Calculation method
Eye Irrit. 2; H319	Calculation method
Skin Sens. 1; H317	Calculation method
STOT SE 3; H335	Calculation method

Relevant H and EUH statements (number and full text)

- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H410 Very toxic to aquatic life with long lasting effects.

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Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)