

Safety Data Sheet

according to UK REACH Regulation

james-2

Revision date: 03.05.2023

Product code: D300045

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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**

Light-curing, solvent-free 1-component restorative adhesive in total-etch technique for enamel and dentin.

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
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements**GB CLP Regulation****Hazard components for labelling**2-hydroxyethyl methacrylate
Aliphatic urethane dimethacrylate; 7,7,9(or 7,9,9)
-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate
Hydroxypropyl Methacrylate**Signal word:** Warning**Pictograms:****Hazard statements**

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.

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Precautionary statements

P273	Avoid release to the environment.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves and eye/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash 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)			
1830-78-0	Glycerol Dimethacrylate			10 - < 25 %
	217-388-4			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
868-77-9	2-hydroxyethyl methacrylate			10 - < 25 %
	212-782-2	607-124-00-X		
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H315 H319 H317			
72869-86-4	Aliphatic urethane dimethacrylate; 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diylbismethacrylate			10 - < 25 %
	276-957-5		01-2120751202-68	
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
27813-02-1	Hydroxypropyl Methacrylate			10 - < 25 %
	248-666-3		01-2119490226-37	
	Eye Irrit. 2, Skin Sens. 1; H319 H317			
	Acrylpolymer; Degacryl 4779 L			10 - < 25 %
	Eye Irrit. 2; H319			
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.

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Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
1830-78-0	217-388-4	Glycerol Dimethacrylate	10 - < 25 %
		oral: LD50 = 2500 mg/kg	
868-77-9	212-782-2	2-hydroxyethyl methacrylate	10 - < 25 %
		oral: LD50 = 5050 mg/kg	
72869-86-4	276-957-5	Aliphatic urethane dimethacrylate; 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diylbismethacrylate	10 - < 25 %
		dermal: LD50 = >5000 mg/kg; oral: LD50 = >5000 mg/kg	
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 polyethylene glycol, followed by plenty of water. 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 plenty 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

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. Vapours can form explosive mixtures with air.

5.3. Advice for firefighters

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

Additional information

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

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.

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6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). 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. Do not breathe gas/fumes/vapour/spray.

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 or drink.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Hints on joint storage

No special measures are necessary.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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

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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

Wear suitable 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: liquid
 Colour: yellow

Melting point/freezing point:	not determined	Test method
Boiling point or initial boiling point and boiling range:	100 °C	
Flammability:	not applicable	
Lower explosion limits:	not determined	
Upper explosion limits:	not determined	
Flash point:	95 °C	ASTM D 56
Auto-ignition temperature:	355 °C	
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
 (at 20 °C)

Density: 1.1 g/cm³

Relative vapour density: not determined

9.2. Other information

Information with regard to physical hazard classes

Self-ignition temperature

Solid: not applicable
 Gas: not applicable

Oxidizing properties
 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

Sensitivity to light.

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10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

UV-radiation/sunlight.

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
1830-78-0	Glycerol Dimethacrylate				
	oral	LD50 2500 mg/kg			
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50 5050 mg/kg	Ratte		
72869-86-4	Aliphatic urethane dimethacrylate; 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate				
	oral	LD50 >5000 mg/kg	Ratte		
	dermal	LD50 >5000 mg/kg	Ratte		
128-37-0	Butylated hydroxitoluene				
	oral	LD50 >6000 mg/kg	rat		OECD 401

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (2-hydroxyethyl methacrylate; Aliphatic urethane dimethacrylate; 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate; Hydroxypropyl Methacrylate)

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

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

STOT-repeated exposure

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

Aspiration hazard

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

Additional information on tests

The mixture is classified as hazardous according to Directive 1999/45/EC.

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SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
868-77-9	2-hydroxyethyl methacrylate					
	Acute fish toxicity	LC50	227 mg/l	96 h	Pimephales promelas	
72869-86-4	Aliphatic urethane dimethacrylate; 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diylbismethacrylate					
	Acute fish toxicity	LC50	10.1 mg/l	96 h	fish	OECD 203
	Acute crustacea toxicity	EC50	1.2 mg/l	48 h	Daphnia magna	OECD 202

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
868-77-9	2-hydroxyethyl methacrylate	0,47

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

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

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

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

Other applicable information (land transport)

No dangerous good in sense of these transport regulations.

Marine transport (IMDG)

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Other applicable information (marine transport)

No dangerous good in sense of these transport regulations.

Air transport (ICAO-TI/IATA-DGR)

Other applicable information (air transport)

No dangerous good in sense of these transport regulations.

14.6. Special precautions for user

No information available.

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

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

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):

1 - slightly hazardous to water

15.2. Chemical safety assessment

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

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

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
Aquatic Chronic 3; H412	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.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

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Further Information

@1604.B160022

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