

Safety Data Sheet

according to Regulation (EC) Nr. 1907/2006

Megafill MH

Revision date: 26.09.2023

Product code: 2MMH

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

1.1. Product identifier

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Product group: Composite

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

Use of the substance/mixture

For restorations of cavity classes I; II; III; IV; V, aesthetic restorations, diastema, enamel hypoplasia and discoloration.

Uses advised against

Application of eugenol containing material, specifically base liners, is not indicated, it will inhibit the polymerization.

1.3. Details of the supplier of the safety data sheet

Company name:	MEGADENTA Dentalprodukte GmbH	
Street:	Carl-Eschebach-Str. 1A	
Place:	01454 Radeberg, Germany	
Telephone:	+49-3528 4530	Telefax: +49-3528 45321
e-mail:	info@megadenta.de	
Internet:	www.megadenta.de	

1.4. Emergency telephone number:

+49-3528 453-0 (just during usual office time: GMT+1)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1907/2006

Eye Dam. 1; H318
Skin Sens. 1; H317
Aquatic Chronic 2; H411

Full text of hazard statements: see SECTION 16.

2.2. Label elements

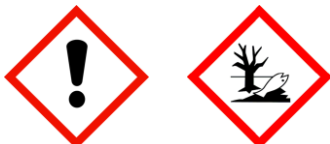
Regulation (EC) No 1907/2006

Hazard components for labelling

Bisphenol-A-bis-(2-hydroxypropyl)methacrylate
Triethylene glycol dimethacrylate

Signal word: Danger

Pictograms:



Hazard statements

May cause an allergic skin reaction.
Causes serious eye damage.
Toxic to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment.
Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

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IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER/doctor.
Collect spillage.

Additional advice on labelling

Medical devices (93/42/EWG) which are invasive or used in direct phys. contact with the human body, are exempted from provisions of Reg. (EC) No 1272/2008 (CLP/GHS) if they are in finished state and intended for the final user.

2.3. Other hazards

The non-polymerized material could irritate skin due to longer contact.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Material contains dimethacrylates, Dental glass, Silica, photochemical Initiatores, Stabilisators, Iron oxide pigments

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
72869-86-4	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-dioldimethacrylate			10 - < 15 %
	276-957-5			
	Aquatic Chronic 3; H412			
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate			5 - < 10 %
	Acute Tox. 4, Eye Dam. 1, Skin Sens. 1, Aquatic Chronic 1; H302 H318 H317 H410			
109-16-0	Triethylene glycol dimethacrylate			1 - < 5 %
	203-652-6		01-2119969287-21	
	Skin Sens. 1; H317			
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate			< 0.1 %
	244-289-3		01-2120766649-35	
	Repr. 1B, Aquatic Acute 1; H360 H400			

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	
72869-86-4	276-957-5	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-dioldimethacrylate	10 - < 15 %
		oral: LD50 = >2000 mg/kg	
1565-94-2		Bisphenol-A-bis-(2-hydroxypropyl)methacrylate	5 - < 10 %
		oral: LD50 = >5000 mg/kg	
109-16-0	203-652-6	Triethylene glycol dimethacrylate	1 - < 5 %
		dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg	
21245-02-3	244-289-3	2-Ethylhexyl-p-dimethylaminobenzoate	< 0.1 %
		dermal: LD50 = >2000 mg/kg; oral: LD50 = 14900 mg/kg	

SECTION 4: First aid measures



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4.1. Description of first aid measures

General information

Polymerized material is non-hazardous.

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

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

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.

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. 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.

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

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

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Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid dust formation. Do not breathe dust. The unprotected substance must not be exposed to the light before processing, because it polymerizes. Only adequately trained personnel should handle this product. For use in dentistry only.

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. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations. Light-sensitive substance. Protect from exposure to the light. Store not above 25°C.

Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

For filling of cavities in the anterior and posterior region, comply with professional industrial hygiene.

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

DNEL/DMEL values

CAS No	Substance	Exposure route	Effect	Value
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate			
	Worker DNEL, long-term	inhalation	systemic	0,5 mg/m ³
	Worker DNEL, long-term	dermal	systemic	6,7 mg/kg bw/day

PNEC values

CAS No	Substance	Value
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate	
	Freshwater	0 mg/l
	Freshwater (intermittent releases)	0 mg/l
	Marine water	0 mg/l
	Freshwater sediment	0,042 mg/kg
	Marine sediment	0,004 mg/kg
	Micro-organisms in sewage treatment plants (STP)	100 mg/l
	Soil	0,008 mg/kg

8.2. Exposure controls

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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

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:	solid paste	
Colour:	tooth colored yellowish	
Odour:	practically odorless	
		Test method
Melting point/freezing point:		not determined
Boiling point or initial boiling point and boiling range:		not determined
Flammability:		not determined not applicable
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Flash point:	> 150 °C	ASTM D 3278
Auto-ignition temperature:		ASTM D 1929
Decomposition temperature:		not determined
pH-Value:		not determined
Viscosity / kinematic:		ISO 3219
Water solubility:	The study does not need to be conducted because the substance is known to be insoluble in water.	OECD 116
Solubility in other solvents	not determined	
Partition coefficient n-octanol/water:		not determined
Vapour pressure: (at 20 °C)	<1 hPa	DIN 51640
Density:	1,77 g/cm ³	
Relative vapour density:	not determined	

9.2. Other information

Information with regard to physical hazard classes

Self-ignition temperature

Solid:

not determined

Gas:

not applicable

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Oxidizing properties
Not oxidising.

Other safety characteristics

Evaporation rate:

not determined

Solid content:

not determined

Flow time:

3 DIN EN ISO 2431

SECTION 10: Stability and reactivity

10.1. Reactivity

Material will polymerize when exposed to daylight.

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

Direct light.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

Further information

With incomplete combustion toxic gases such as carbon monoxide may be generated.

SECTION 11: Toxicological information

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

ATEmix tested

	Dose	Species	Source
LD50, oral	5000 mg/kg	Ratte	Literature

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Acute toxicity

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
72869-86-4	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-dioldimethacrylate				
	oral	LD50 >2000 mg/kg	Rat	OECD 401, limit test	
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate				
	oral	LD50 >5000 mg/kg	Rat	Manufacturer	
109-16-0	Triethylene glycol dimethacrylate				
	oral	LD50 >5000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	mouse		
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate				
	oral	LD50 14900 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		

Additional information on tests

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

Practical experience

When used and handled according to specifications, the product gives to the present knowledge and experience no adverse health effects .

SECTION 12: Ecological information

12.1. Toxicity

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
72869-86-4	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-dioldimethacrylate					
	Acute fish toxicity	LC50	10,1 mg/l	96 h	Brachydanio rerio	OECD 203
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate					
	Acute fish toxicity	LC50	>100 mg/l	96 h	Poecilia reticulata (Guppy)	Manufacturer
109-16-0	Triethylene glycol dimethacrylate					
	Acute fish toxicity	LC50	16,4 mg/l	96 h	Danio rerio	OECD-Test Nr. 203
	Acute algae toxicity	ErC50	>100 mg/l		Pseudokirchneriella subcapitata	OECD-Test Nr. 201
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate					
	Acute fish toxicity	LC50	0,235 mg/l	96 h		Manufacturer
	Acute algae toxicity	ErC50	>0,015 mg/l	72 h	Pseudokirchneriella subcapitata	
	Acute crustacea toxicity	EC50	>0,031 mg/l	48 h	Daphnia magna	
	Acute bacteria toxicity	(EC50	>1000 mg/l)	3 h		

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
72869-86-4	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-dioldimethacrylate	3,39
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate	4,63
109-16-0	Triethylene glycol dimethacrylate	2,3
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate	>6,2

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

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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.

List of Wastes Code - residues/unused products

200139 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); Plastics

Contaminated packaging

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

SECTION 14: Transport information

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 75

2010/75/EU (VOC): 5,738 % (101,554 g/l)

2004/42/EC (VOC): 4,59 % (81,241 g/l)

Information according to 2012/18/EU (SEVESO III): E2 Hazardous to the Aquatic Environment

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): 3 - highly 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

Changes

This data sheet contains changes from the previous version in section(s): 2.

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%

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

Classification	Classification procedure
Eye Dam. 1; H318	Calculation method
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 2; H411	Calculation method

Relevant H and EUH statements (number and full text)

- Harmful if swallowed.
- May cause an allergic skin reaction.
- Causes serious eye damage.
- May damage fertility or the unborn child.
- Very toxic to aquatic life.
- Very toxic to aquatic life with long lasting effects.
- Toxic to aquatic life with long lasting effects.
- Harmful to aquatic life with long lasting effects.

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.)