

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

**Megafill MH**

Revision date: 17.02.2021

Product code: 2MMH

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

Megafill MH

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. 1272/2008**

Hazard categories:

Serious eye damage/eye irritation: Eye Dam. 1

Respiratory or skin sensitisation: Skin Sens. 1

Hazardous to the aquatic environment: Aquatic Chronic 2

Hazard Statements:

Causes serious eye damage.

May cause an allergic skin reaction.

Toxic to aquatic life with long lasting effects.

**2.2. Label elements****Regulation (EC) No. 1272/2008****Hazard components for labelling**

Bisphenol-A-bis-(2-hydroxypropyl)methacrylate

Triethylene glycol dimethacrylate

**Signal word:** Danger**Pictograms:****Hazard statements**

H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H411	Toxic to aquatic life with long lasting effects.

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**Precautionary statements**

P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P391	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 Initiators, Stabilisators, Iron oxide pigments

**Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
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.

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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	
72869-86-4	276-957-5	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxo-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****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**

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**General measures**

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****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.

**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 <sup>3</sup>	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 <sup>3</sup>
	Worker DNEL, long-term	dermal	systemic	6,7 mg/kg bw/day

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**PNEC values**

CAS No	Substance	
Environmental compartment		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****Appropriate engineering controls**

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

**Protective and hygiene measures**

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.

**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**

pH-Value: not determined

**Changes in the physical state**

Melting point: not determined  
 Boiling point or initial boiling point and boiling range: not determined

Flash point: > 150 °C ASTM D 3278

**Flammability**

Solid/liquid: not determined

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Gas:	not applicable
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Auto-ignition temperature:	ASTM D 1929
<b>Self-ignition temperature</b>	
Solid:	not determined
Gas:	not applicable
Decomposition temperature:	not determined
<b>Oxidizing properties</b>	
Not oxidising.	
Vapour pressure: (at 20 °C)	<1 hPa DIN 51640
Density:	1,77 g/cm <sup>3</sup>
Water solubility:	The study does not need to be conducted because the substance is known to be insoluble in water. OECD 116
<b>Solubility in other solvents</b>	
not determined	
Partition coefficient n-octanol/water:	not determined
Viscosity / kinematic:	ISO 3219
Flow time:	3 DIN EN ISO 2431
Relative vapour density:	not determined
Evaporation rate:	not determined
<b>9.2. Other information</b>	
Solid content:	not determined

**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 Regulation (EC) No 1272/2008**

ATEmix tested

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LD50, oral	Dose 5000 mg/kg	Species Ratte	Source 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 mg/kg >2000	Rat	OECD 401, limit test	
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate				
	oral	LD50 mg/kg >5000	Rat	Manufacturer	
109-16-0	Triethylene glycol dimethacrylate				
	oral	LD50 mg/kg >5000	Rat		
	dermal	LD50 mg/kg >2000	mouse		
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate				
	oral	LD50 mg/kg 14900	Rat		
	dermal	LD50 mg/kg >2000	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 mg/l	10,1	96 h	Brachydanio rerio	OECD 203
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate					
	Acute fish toxicity	LC50 mg/l	>100	96 h	Poecilia reticulata (Guppy)	Manufacturer
109-16-0	Triethylene glycol dimethacrylate					
	Acute fish toxicity	LC50 mg/l	16,4	96 h	Danio rerio	OECD-Test Nr. 203
	Acute algae toxicity	ErC50 mg/l	>100		Pseudokirchneriella subcapitata	OECD-Test Nr. 201
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate					
	Acute fish toxicity	LC50 mg/l	0,235	96 h		Manufacturer
	Acute algae toxicity	ErC50 mg/l	>0,015	72 h	Pseudokirchneriella subcapitata	
	Acute crustacea toxicity	EC50 mg/l	>0,031	48 h	Daphnia magna	
	Acute bacteria toxicity	(>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 product has not been tested.

#### **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.

##### **List of Wastes Code - residues/unused products**



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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**

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): 2,3,6,7,9.

**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 Regulation (EC) No. 1272/2008 [CLP]**

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

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**Relevant H and EUH statements (number and full text)**

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H360	May damage fertility or the unborn child.
H400	Very toxic to aquatic life.
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.

**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.

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