

Safety Data Sheet

according to Regulation (EC) No 1907/2006

P-Fill

Revision date: 09.03.2017

Product code: 2PF

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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 fillings of class I, II and V.

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:

May cause an allergic skin reaction.

Causes serious eye damage.

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.

Precautionary statements

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
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P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
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.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

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	

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	

SECTION 4: First aid measures**4.1. Description of first aid measures**

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General information

Polymerized material is non-hazardous.

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 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.

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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

none

7.3. Specific end use(s)

For cavity filling of classes I, II and V. 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

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

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Melting point:	not determined
Boiling point or initial boiling point and boiling range:	283 °C
Flash point:	> 150,0000001 °C ASTM D 3278

Flammability

Solid/liquid:	not determined
Gas:	not applicable
Lower explosion limits:	not determined
Upper explosion limits:	not determined

Self-ignition temperature

Solid:	not determined
Gas:	not applicable
Decomposition temperature:	not determined

Oxidizing properties

Not oxidising.

Vapour pressure: (at 20 °C)	0,077 hPa DIN 51640
Density:	1,99 g/cm ³
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
Relative vapour density:	not determined
Evaporation rate:	not determined

9.2. Other information

Solid content:	76,87 %
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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

none

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

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11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**Acute toxicity**

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

ATEmix tested

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

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-dioxo-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		

Irritation and corrosivity

Causes serious eye damage.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Sensitising effects

May cause an allergic skin reaction. (Bisphenol-A-bis-(2-hydroxypropyl)methacrylate; Triethylene glycol dimethacrylate)

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 regulation (EC) No 1272/2008 [CLP].

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

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

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

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

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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): 5,768 % (114,783 g/l)

2004/42/EC (VOC): 4,66 % (92,734 g/l)

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):
1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16.

Abbreviations and acronymsADR: 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%

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.
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 above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material. Diese Angaben beschreiben ausschließlich die Sicherheitserfordernisse des Produktes und stützen sich auf den heutigen Stand unserer Kenntnisse. Sie stellen keine Zusicherung von Eigenschaften des beschriebenen Produktes im Sinne der gesetzlichen Gewährleistungsvorschriften dar.

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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.)