

Safety Data Sheet

according to Regulation (EC) No 1907/2006

C-Seal

Revision date: 07.09.2018

Product code: 2CSEAL

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

C-Seal

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

For sealing of fissures, for caries prophylaxis, for the restoration of small carious defects, for sealing of fillings of composite or cement (moisture protection).

Uses advised against

C-seal should not be used together with eugenol underfillings.

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:

Skin corrosion/irritation: Skin Irrit. 2

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 skin irritation.

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 epoxyate dimethacrylate

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

diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

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

H315	Causes skin irritation.
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.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

Material contains dimethacrylates, Dental glass, photochemical Initiatores, Stabilisators, Fluoride.

Hazardous components

CAS No	Chemical name	Quantity
	EC No	
	Index No	
	REACH No	
	GHS Classification	
41637-38-1	Bisphenol A epoxyate dimethacrylate	15 - < 20 %
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335	
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate	15 - < 20 %
	Acute Tox. 4, Eye Dam. 1, Skin Sens. 1, Aquatic Chronic 1; H302 H318 H317 H410	
6818-37-7	2,2'-[[3-[2-Hydroxyethyl]octadecylamino]propyl]imino]bis-ethanol Dihydrofluorid 25-50%	1 - < 5 %
	229-891-6	
	Acute Tox. 4; H302	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	< 1 %
	278-355-8	015-203-00-X
	Repr. 2; H361f	
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate	< 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	
41637-38-1		Bisphenol A epoxyate dimethacrylate	15 - < 20 %
		dermal: LD50 = 2000 mg/kg; oral: LD50 = 2000 mg/kg	
1565-94-2		Bisphenol-A-bis-(2-hydroxypropyl)methacrylate	15 - < 20 %
		oral: LD50 = >5000 mg/kg	
6818-37-7	229-891-6	2,2'-[[3-[2-Hydroxyethyl]octadecylamino]propyl]imino]bis-ethanol Dihydrofluorid	1 - < 5 %
		25-50%	
		oral: LD50 = 400 mg/kg	
75980-60-8	278-355-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	< 1 %
		inhalation: Data lacking (gases); oral: LD50 = >5000 mg/kg	
21245-02-3	244-289-3	2-Ethylhexyl-p-dimethylaminobenzoate	< 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**

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.

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.

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
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			
Worker DNEL, long-term		dermal	systemic	0,233 mg/kg bw/day
Consumer DNEL, long-term		inhalation	systemic	0,145 mg/m ³
Consumer DNEL, long-term		dermal	systemic	0,0833 mg/kg bw/day
Consumer DNEL, long-term		oral	systemic	0,0833 mg/kg bw/day
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

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PNEC values

CAS No	Substance	Value
Environmental compartment		
41637-38-1	Bisphenol A epoxyate dimethacrylate	
Micro-organisms in sewage treatment plants (STP)		14,3 mg/l
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:	flowable paste	
Colour:	white or colourless	
Odour:	characteristic	
pH-Value:		not determined

Changes in the physical state

Melting point:		not determined
Boiling point or initial boiling point and boiling range:		211 °C
Flash point:		113 °C

Flammability

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Solid/liquid: not applicable

Gas: not applicable

Lower explosion limits: not determined

Upper explosion limits: not determined

Self-ignition temperature

Solid: not applicable

Gas: not applicable

Decomposition temperature: not determined

Oxidizing properties

Not oxidising.

Vapour pressure:
(at 20 °C) <1 hPaDensity (at 20 °C): 1,52 g/cm³

Water solubility: practically insoluble

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: 48,56 %

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

Direct light.

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 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	

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
41637-38-1	Bisphenol A epoxyate dimethacrylate				
	oral	LD50 2000 mg/kg	Rat		OECD Richtlinie 412
	dermal	LD50 2000 mg/kg	rat (6h)		OECD Prüfrichtlinie 402
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate				
	oral	LD50 >5000 mg/kg	Rat	Manufacturer	
6818-37-7	2,2'-[[3-[2-Hydroxyethyl]octadecylamino]propyl]imino]bis-ethanol Dihydrofluorid 25-50%				
	oral	LD50 400 mg/kg	Rat	Manufacturer	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
	oral	LD50 >5000 mg/kg	Rat		
	inhalation	Data lacking			
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate				
	oral	LD50 14900 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		

Irritation and corrosivity

Causes skin irritation.

Causes serious eye damage.

Sensitising effects

May cause an allergic skin reaction. (Bisphenol A epoxyate dimethacrylate; Bisphenol-A-bis-(2-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 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
41637-38-1	Bisphenol A epoxyate dimethacrylate					
	Acute fish toxicity	LC50 >100 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)		OECD Prüfrichtlinie 203
	Acute algae toxicity	ErC50 >100 mg/l	72 h	Pseudokirchneriella subcapitata		OECD Prüfrichtlinie 201
	Acute crustacea toxicity	EC50 >100 mg/l	48 h	Daphnia magna (Big water flea)		OECD Prüfrichtlinie 202
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate					
	Acute fish toxicity	LC50 >100 mg/l	96 h	Poecilia reticulata (Guppy)	Manufacturer	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide					
	Acute fish toxicity	LC50 6,53 mg/l	96 h	Oryzias latipes		
	Acute algae toxicity	ErC50 2,01 mg/l	72 h	Pseudokirchneriella subcapitata	OECD 201	
	Acute crustacea toxicity	EC50 3,53 mg/l	48 h	Daphnia magna	OECD Guideline 202	
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	(>1000 mg/l)	3 h			

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name				
	Method	Value	d	Source	
	Evaluation				
41637-38-1	Bisphenol A epoxyate dimethacrylate				
	OECD Richtlinie 301 D	24%	28		
	Not easily biodegradable. Potentially bioaccumulative.				

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
41637-38-1	Bisphenol A epoxyate dimethacrylate	5,3-5,62
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate	4,63
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	3,257
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.

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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

List of Wastes Code - used product

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

List of Wastes Code - contaminated packaging

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**Land transport (ADR/RID)****14.1. UN 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.**14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: No

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**

Restrictions on use (REACH, annex XVII):

Entry 3

2010/75/EU (VOC): 16,448 % (250,008 g/l)

2004/42/EC (VOC): 18,345 % (278,841 g/l)

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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):

1 - slightly 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): 1,2,3,4,6,9,11,15,16.

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%

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Skin Irrit. 2; H315	Calculation method
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)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360	May damage fertility or the unborn child.
H361f	Suspected of damaging fertility.
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.

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.)