



**Safety data sheet
according to 1907/2006/EC, Article 31**

Printing date 16.11.2020

Version number 5

Revision: 16.11.2020

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

· **1.1 Product identifier**

· Trade name: **Signum ceramis**

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Veneering resin

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522

· **Informing department:** E-Mail: msds@kulzer-dental.com

· **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**

Skin Sens. 1 H317 May cause an allergic skin reaction.

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

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard-determining components of labelling:**

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

Bisphenol A Diglycidylether Diacrylate (BADGE-DA)

triethylen glycol dimethacrylate

2-propenoic acid, 1,1'-[(1-methyl-1,2-ethanediyl)bis[oxy(methyl-2,1-ethanediyl)]]ester, reaction products with diethylamine

· **Hazard statements**

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P273 Avoid release to the environment.

P280 Wear protective gloves / eye protection.

· **Additional information:**

8.3 % of the mixture consists of component(s) of unknown toxicity.

Contains 8.3 % of components with unknown hazards to the aquatic environment.

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

GB

(Contd. on page 2)



**Safety data sheet
according to 1907/2006/EC, Article 31**

Printing date 16.11.2020

Version number 5

Revision: 16.11.2020

Trade name: Signum ceramis

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: -

Dangerous components:

CAS: 72869-86-4 EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-XXXX	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate ----- Aquatic Chronic 2, H411 Skin Sens. 1B, H317	≥5-<25%
CAS: 55818-57-0 EINECS: 225-144-3 Reg.nr.: 01-2119490020-53-XXXX	Bisphenol A Diglycidylether Diacrylate (BADGE-DA) ----- Aquatic Chronic 2, H411 Skin Sens. 1, H317	≥2.5-≤10%
CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-0000	triethylen glycol dimethacrylate ----- Skin Sens. 1B, H317	≥1-≤5%
CAS: 111497-86-0 EC number: 601-101-8 Reg.nr.: 01-2119961351-42-XXXX	2-propenoic acid, 1,1'-[(1-methyl-1,2-ethanediy) bis[oxy(methyl-2,1-ethanediy)]]ester, reaction products with diethylamine ----- Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1B, H317	≥0.1-<1%

Additional information For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

After inhalation Supply fresh air; consult doctor in case of symptoms.

After skin contact

Instantly wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

After eye contact

Rinse opened eye for several minutes under running water. Then consult doctor.

After swallowing

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult doctor.

4.2 Most important symptoms and effects, both acute and delayed Allergic reactions

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents

Use fire fighting measures that suit the environment.

CO₂, extinguishing powder or water jet. Fight larger fire with alcohol-resistant foam.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

5.3 Advice for firefighters

Protective equipment: No special measures required.

Additional information -

GB
(Contd. on page 3)



Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.11.2020

Version number 5

Revision: 16.11.2020

Trade name: Signum ceramis

(Contd. of page 2)

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective clothing.
- **6.2 Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
- **6.4 Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.
-

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Ensure good ventilation/exhaustion at the workplace.
 - **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
 - **Components with critical values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Not required.

· DNELs		
55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)		
Dermal	worker industr., l.te., syst.	17.5 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	122.5 mg/m3 (nd)
109-16-0 triethylen glycol dimethacrylate		
Dermal	worker industr., l.te., syst.	13.9 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	48.5 mg/m3 (nd)
· PNECs		
55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)		
freshwater	0.1 mg/l (nd)	
marine water	0.01 mg/l (nd)	
interm. wat. release	1 mg/l (nd)	
STP	10 mg/l (nd)	
sedim., dw, fre.wat.	35.8 mg/Kg (nd)	
soil,dw	71 mg/Kg (nd)	

(Contd. on page 4)



Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.11.2020

Version number 5

Revision: 16.11.2020

Trade name: Signum ceramis

(Contd. of page 3)

109-16-0 triethylen glycol dimethacrylate

marine water	0.0164 mg/l (nd)
sedim., dw, fre.wat.	1.85 mg/Kg (nd)
sedim., dw, mar.wat.	0.185 mg/Kg (nd)
soil,dw	0.274 mg/Kg (nd)

· **Additional information:** The lists that were valid during the compilation were used as basis.

· **8.2 Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.

· **Breathing equipment:**

Not necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

· **Protection of hands:**

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

Check protective gloves prior to each use for their proper condition.
recommended

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**

Butyl rubber, BR
Nitrile rubber, NBR

· **Eye protection:** Tightly sealed safety glasses.

· **Body protection:** Light weight protective clothing

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:** Pasty
· **Colour:** According to product specification

· **Smell:** Ester-like

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· **Melting point/freezing point:** Not determined

· **Initial boiling point and boiling range:** 100 °C

· **Flash point:** 101 °C

· **Inflammability (solid, gaseous)** Not applicable.

(Contd. on page 5)



Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.11.2020

Version number 5

Revision: 16.11.2020

Trade name: Signum ceramis

(Contd. of page 4)

· Ignition temperature:	400 °C
· Decomposition temperature:	Not determined.
· Self-inflammability:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. Not determined.
· Critical values for explosion:	
· Lower:	Not determined.
· Upper:	Not determined.
· Steam pressure at 20 °C:	40 hPa
· Density at 20 °C	1.86 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
· dynamic:	Not determined.
· kinematic:	Not determined.
· Solvent content:	
· Water:	3.4-<4.4 %
· Solids content:	70.2 %
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
 - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None
 - **Additional information:** -

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
 - **Acute toxicity** Based on available data, the classification criteria are not met.

· LD/LC50 values that are relevant for classification:		
65997-18-4 Glas / Fritte		
Oral	LD50	>2,000 mg/kg (rat)
7631-86-9 silicon dioxide, chemically prepared		
Oral	LD50	>5,000 mg/kg (rat)

(Contd. on page 6)



Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.11.2020

Version number 5

Revision: 16.11.2020

Trade name: Signum ceramis

(Contd. of page 5)

Dermal	LD50	>5,000 mg/kg (rabbit)
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate		
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)
2530-85-0 3-trimethoxysilylpropyl methacrylate		
Oral	LD50	>2,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (can)
55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)		
Oral	LD0	>2,000 mg/kg (rat) (OECD 401)
Dermal	LD0	>2,000 mg/kg (rat) (OECD 402)
Sensitisation	Sensib.	(human) (mouse) (LLNA)
109-16-0 triethylen glycol dimethacrylate		
Oral	LD50	8,300 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (mouse)
111497-86-0 2-propenoic acid, 1,1'-[(1-methyl-1,2-ethanediyl)bis[oxy(methyl-2,1-ethanediyl)]] ester, reaction products with diethylamine		
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)

- **Primary irritant effect:**
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation**
Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
 - **Carcinogenicity** Based on available data, the classification criteria are not met.
 - **Reproductive toxicity** 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.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	
LC50/96h	10.1 mg/l (fish)
55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)	
EC50/72h	>110 mg/l (algae) (OECD 201)
LC50/96h	>79 mg/l (fish) (OECD 203)
109-16-0 triethylen glycol dimethacrylate	
EC50/72h	>100 mg/l (algae)

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.

(Contd. on page 7)



**Safety data sheet
according to 1907/2006/EC, Article 31**

Printing date 16.11.2020

Version number 5

Revision: 16.11.2020

Trade name: Signum ceramis

(Contd. of page 6)

- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
 - **General notes:**
Do not allow product to reach ground water, water bodies or sewage system.
Danger to drinking water if even small quantities leak into soil.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Disposal must be made according to official regulations.
- **European waste catalogue**

18 01 06*	chemicals consisting of or containing hazardous substances
-----------	--
- **Uncleaned packagings:**
 - **Recommendation:**
Disposal must be made according to official regulations.
Non contaminated packagings can be used for recycling.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN-Number
· ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · 14.4 Packing group
· ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards:
· Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

GB
(Contd. on page 8)



**Safety data sheet
according to 1907/2006/EC, Article 31**

Printing date 16.11.2020

Version number 5

Revision: 16.11.2020

Trade name: Signum ceramis

(Contd. of page 7)

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **Directive 2012/18/EU**
 - **Named dangerous substances - ANNEX I** None of the ingredients is listed.
 - **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
 - H315 Causes skin irritation.
 - H317 May cause an allergic skin reaction.
 - H319 Causes serious eye irritation.
 - H411 Toxic to aquatic life with long lasting effects.
- **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 Harmonised 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 (division of the American Chemical Society)
 - DNEL: Derived No-Effect Level (REACH)
 - PNEC: Predicted No-Effect Concentration (REACH)
 - LC50: Lethal concentration, 50 percent
 - LD50: Lethal dose, 50 percent
 - PBT: Persistent, Bioaccumulative and Toxic
 - vPvB: very Persistent and very Bioaccumulative
 - Skin Irrit. 2: Skin corrosion/irritation – Category 2
 - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 - Skin Sens. 1: Skin sensitisation – Category 1
 - Skin Sens. 1B: Skin sensitisation – Category 1B
 - Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
 - Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
- *** Data compared to the previous version altered.**

GB