



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

Printing date 13.02.2023

Version number 5 (replaces version 4)

Revision: 13.02.2023

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

· **1.1 Product identifier**

· Trade name: **Signum composite ...**

· - dentine, margin, enamel, effect

· **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](mailto: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 Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 2 H411 Toxic 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 GB CLP regulation.

· **Hazard pictograms**



GHS07 GHS09

· **Signal word** Warning

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

1,12-Dodecanediol dimethacrylate

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

triethylen glycol dimethacrylate

· **Hazard statements**

H317 May cause an allergic skin reaction.

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P273 Avoid release to the environment.

P280 Wear protective gloves / eye protection.

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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**SECTION 3: Composition/information on ingredients**

**3.2 Mixtures**

**Description:** Product based on methacrylates

**Dangerous components:**

CAS: 72829-09-5 EINECS: 276-900-4	1,12-Dodecanediol dimethacrylate Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1) Skin Sens. 1B, H317	≥10-<25%
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 EUH204	≥10-<25%
CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-xxxx	triethylen glycol dimethacrylate Skin Sens. 1B, H317	≥1-≤5%

**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**

**General information** No special measures required.

**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**

No further relevant information available.

**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**

CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.  
Use fire fighting measures that suit the environment.

**5.2 Special hazards arising from the substance or mixture**

No further relevant information available.

**5.3 Advice for firefighters**

**Protective equipment:** No special measures required.

**Additional information** -

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**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Avoid contact with eyes and skin.
- **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**  
No dangerous materials are released.  
See Section 8 for information on personal protection equipment.

**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** No special measures required.
  - **Information about protection against explosions and fires:** No special measures required.
- **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:** Store cool (not above 25 °C).
- **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.

· <b>DNELs</b>		
<b>72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate</b>		
Oral	general population, long term, systemic	0.3 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	1.3 mg/Kg/d (not defined)
	general population, long term, systemic	0.7 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	3.3 mg/m3 (not defined)
	general population, long term, systemic	0.6 mg/m3 (not defined)
<b>109-16-0 triethylen glycol dimethacrylate</b>		
Oral	general population, long term, systemic	8.33 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.9 mg/Kg/d (not defined)
	general population, long term, systemic	8.33 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	48.5 mg/m3 (not defined)
	general population, long term, systemic	14.5 mg/m3 (not defined)
· <b>PNECs</b>		
<b>72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate</b>		
freshwater		0.01 mg/l (not defined)

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marine water	0.001 mg/l (not defined)
sewage treatment plant	3.61 mg/l (not defined)
sediment, dry weight, freshwater	4.56 mg/Kg (not defined)
sediment, dry weight, marine water	0.46 mg/Kg (not defined)
soil, dry weight	0.91 mg/Kg (not defined)
<b>109-16-0 triethylen glycol dimethacrylate</b>	
freshwater	0.016 mg/l (not defined)
marine water	0.002 mg/l (not defined)
sewage treatment plant	1.7 mg/l (not defined)
sediment, dry weight, freshwater	0.185 mg/Kg (not defined)
sediment, dry weight, marine water	0.018 mg/Kg (not defined)
soil, dry weight	0.027 mg/Kg (not defined)

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

· **8.2 Exposure controls**

· **Appropriate engineering controls** No further data; see item 7.

· **Individual protection measures, such as 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 if room is well-ventilated.

· **Hand protection**

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 through 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/face 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**

· **Physical state**

Fluid

· **Colour:**

Brown

White

Pink

Colourless

· **Smell:**

Odourless

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· <b>Odour threshold:</b>	Not determined.
· <b>Melting point/freezing point:</b>	Not determined
· <b>Boiling point or initial boiling point and boiling range</b>	250 °C
· <b>Flammability</b>	Not applicable.
· <b>Lower and upper explosion limit</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Flash point:</b>	>100 °C (72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate)
· <b>Decomposition temperature:</b>	Not determined.
· <b>SADT</b>	
· <b>pH</b>	Mixture is non-soluble (in water).
· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not determined.
· <b>dynamic:</b>	Not determined.
· <b>Solubility</b>	
· <b>Water:</b>	Not miscible or difficult to mix
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Steam pressure at 20 °C:</b>	40 hPa
· <b>Density and/or relative density</b>	
· <b>Density at 20 °C</b>	1.450 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.

· <b>9.2 Other information</b>	No further relevant information available.
· <b>Appearance:</b>	
· <b>Form:</b>	Pasty
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Self-flammability:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive. Not determined.
· <b>Solvent content:</b>	
· <b>VOC EU</b>	g/l
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not determined.

· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void

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· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

**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:**  
If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

**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.

· **LD/LC50 values that are relevant for classification:**

**112945-52-5 Amorphous silica**

Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>5,000 mg/kg (rabbit)

**72829-09-5 1,12-Dodecanediol dimethacrylate**

Oral	LD0	>2,000 mg/kg (rat) (OECD 423)
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**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 (rabbit)

**109-16-0 triethylen glycol dimethacrylate**

Oral	LD50	8,300 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (mouse)

- **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.
- **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.

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· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information**

· **12.1 Toxicity**

· **Aquatic toxicity:**

**112945-52-5 Amorphous silica**

LC50/96h >10,000 mg/l (fish) (OECD 203)

EC50 / 24h >1,000 mg/l (daphnia)

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate**

EC50/48h >1.2 mg/l (daphnia) (OECD 202)

LC50/96h 10.1 mg/l (fish) (OECD 203)

ErC50 / 72 h >0.68 mg/l (algae) (OECD 201)

NOEC / 72h 0.21 mg/l (algae) (OECD 201)

**2530-85-0 3-trimethoxysilylpropyl methacrylate**

EC50/48h >100 mg/l (daphnia) (EU C2.)

LC50/96h >100 mg/l (fish) (EU C.1)

**109-16-0 triethylen glycol dimethacrylate**

EC50/21d 51.9 mg/L (daphnia) (OECD 211)

LC50/96h 16.4 mg/l (fish) (OECD 203)

NOEC / 21d 32 mg/l (daphnia) (OECD 211)

ErC50 / 72 h >100 mg/l (algae) (OECD 201)

NOEC / 72h 18.6 mg/l (algae) (OECD 201)

EbC50 / 72h 72.8 mg/l (algae) (OECD 201)

· **12.2 Persistence and degradability**

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate**

Biodegradation 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

**2530-85-0 3-trimethoxysilylpropyl methacrylate**

Biodegradation 69 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

**109-16-0 triethylen glycol dimethacrylate**

Biodegradation 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

· **12.3 Bioaccumulative potential** No further relevant information available.

· **12.4 Mobility in soil** No further relevant information available.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Endocrine disrupting properties**

For information on endocrine disrupting properties see section 11.

· **12.7 Other adverse effects** No further relevant information available.

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**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.

· **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 or ID number**

· **ADR, IMDG, IATA**

UN3082

· **14.2 UN proper shipping name**

· **ADR**

3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,12-Dodecanediol dimethacrylate, 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate)

· **IMDG**

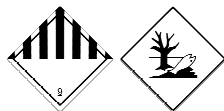
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,12-Dodecanediol dimethacrylate, 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate), MARINE POLLUTANT

· **IATA**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,12-Dodecanediol dimethacrylate, 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate)

· **14.3 Transport hazard class(es)**

· **ADR**



· **Class**

9 (M6) Miscellaneous dangerous substances and articles.

· **Label**

9

· **IMDG, IATA**



· **Class**

9 Miscellaneous dangerous substances and articles.

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· <b>Label</b>	9
· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	III
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	No Symbol (fish and tree)
· <b>Special marking (ADR):</b> · <b>Special marking (IATA):</b>	Symbol (fish and tree) Symbol (fish and tree)
· <b>14.6 Special precautions for user</b> · <b>Kemler Number:</b> · <b>EMS Number:</b> · <b>Stowage Category</b>	Warning: Miscellaneous dangerous substances and articles. 90 F-A, S-F A
· <b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable.
· <b>Transport/Additional information:</b>	-
· <b>ADR</b> · <b>Limited quantities (LQ)</b> · <b>Excepted quantities (EQ)</b>	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· <b>Transport category</b> · <b>Tunnel restriction code</b>	3 (-)
· <b>IMDG</b> · <b>Limited quantities (LQ)</b> · <b>Excepted quantities (EQ)</b>	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· <b>UN "Model Regulation":</b>	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,12-DODECANEDIOL DIMETHACRYLATE, 7,7,9(OR 7,9,9)-TRIMETHYL-4,13-DIOXO-3,14-DIOXA-5,12-DIAZAHEXADECANE-1,16-DIYL BISMETHACRYLATE), 9, III

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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**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**

- H317 May cause an allergic skin reaction.
- 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.
- EUH204 Contains isocyanates. May produce an allergic reaction.

**Abbreviations and acronyms:**

- SADT: Self Accelerating Decomposition Temperature
- ADR: Accord relatif au transport international 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)
- VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
- DNEL: Derived No-Effect Level (UK REACH)
- PNEC: Predicted No-Effect Concentration (UK REACH)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- Skin Sens. 1: Skin sensitisation – Category 1
- Skin Sens. 1B: Skin sensitisation – Category 1B
- Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
- Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
- Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

**\* Data compared to the previous version altered.**