



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

Printing date 10.02.2018

Version number 3

Revision: 10.02.2018

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

- **1.1 Product identifier**
 - **Trade name:** **Signum Composite flow**
- **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:**

triethylen glycol dimethacrylate
- **Hazard statements**

H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P321 Specific treatment (see on this label).
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- **2.3 Other hazards -**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
 - **Description:** -

(Contd. on page 2)

GB



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Version number 3

Revision: 10.02.2018

Trade name: Signum Composite flow

(Contd. of page 1)

· Dangerous components:

CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-0000	triethylen glycol dimethacrylate Skin Sens. 1B, H317	5-10%
CAS: 24650-42-8 EINECS: 246-386-6	2,2-dimethoxy-1,2-diphenylethan-1-one Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0-5%

· 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

· 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

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

CO₂, 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 -

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing.

· 6.2 Environmental precautions:

Do not allow product to reach sewage system or water bodies.

Do not allow to enter the ground/soil.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

Send for recovery or disposal in suitable containers.

· 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.

(Contd. on page 3)



**Safety data sheet
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Version number 3

Revision: 10.02.2018

Trade name: Signum Composite flow

(Contd. of page 2)

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Please observe the additional instructions in the product's instructions for use.

Wear protective equipment. Keep unprotected persons away.

- **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:** 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.

· DNELs

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/m ³ (nd)

· PNECs

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

Wash hands during breaks and at the end of the work.

· **Breathing equipment:** Not required.

· Protection of hands:

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.

(Contd. on page 4)



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

Printing date 10.02.2018

Version number 3

Revision: 10.02.2018

Trade name: Signum Composite flow

(Contd. of page 3)

- **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:** 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:** Fluid
- **Colour:** Cream coloured
- **Smell:** Odourless
- **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

- **Melting point/freezing point:** Not determined
- **Initial boiling point and boiling range:** 255 °C

· **Flash point:** 101 °C

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

· **Ignition temperature:**

- **Decomposition temperature:** Not determined.

· **Self-inflammability:** Product is not selfigniting.

· **Explosive properties:** Product is not explosive.

· **Critical values for explosion:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Steam pressure:** Not determined.

· **Density** Not determined

- **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:** 1,3 %

· **Solids content:** 9,6 %

(Contd. on page 5)



**Safety data sheet
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Version number 3

Revision: 10.02.2018

Trade name: Signum Composite flow

(Contd. of page 4)

· **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:**

109-16-0 triethylen glycol dimethacrylate

Oral LD50 >5,000 mg/kg (rat)

Dermal LD50 >2,000 mg/kg (mouse)

amorphe Kieselsäure

Oral LD50 >5,000 mg/kg (rat)

24650-42-8 2,2-dimethoxy-1,2-diphenylethan-1-one

Oral LD50 >6,000 mg/kg (rat)

Dermal LD50 >7,100 mg/kg (rat)

128-37-0 2,6-di-tert-butyl-p-cresol

Oral LD50 >2,000 mg/kg (rat)

- **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:**

109-16-0 triethylen glycol dimethacrylate

EC50/72h >100 mg/l (algae)

(Contd. on page 6)



**Safety data sheet
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(Contd. of page 5)

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
 - **Ecotoxicological effects:**
 - **Remark:** Harmful to fish
 - **Additional ecological information:**
 - **General notes:**
Avoid transfer into the environment.
Harmful to aquatic organisms
- **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.
 - **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN-Number <ul style="list-style-type: none">· ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name <ul style="list-style-type: none">· ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) <ul style="list-style-type: none">· ADR, ADN, IMDG, IATA· Class | Void |
| · 14.4 Packing group <ul style="list-style-type: none">· ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | Not applicable. |
| · 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 7)



**Safety data sheet
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Trade name: Signum Composite flow

(Contd. of page 6)

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**
 - H317 May cause an allergic skin reaction.
 - H400 Very toxic to aquatic life.
 - H410 Very 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 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 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
- *** Data compared to the previous version altered.**

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