



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

Printing date 27.01.2018

Version number 4

Revision: 27.01.2018


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

- **1.1 Product identifier**
  - **Trade name: Signum cre-active**
  - - colourfluids, transpafluids, gingiva
- **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** Auxiliary for manufacture of dental prothesis
- **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.
  - **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  
diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide
  - **Hazard statements**  
H317 May cause an allergic skin reaction.
  - **Precautionary statements**
    - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
    - P272 Contaminated work clothing should not be allowed out of the workplace.
    - 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:** Product based on methacrylates

(Contd. on page 2)

IRL



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

Printing date 27.01.2018

Version number 4

Revision: 27.01.2018

**Trade name: Signum cre-active**

(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	25-50%
CAS: 75980-60-8 EINECS: 278-355-8 Reg.nr.: 01-2119972295-29	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide Repr. 2, H361f; Aquatic Chronic 2, H411; Skin Sens. 1B, H317	< 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**
  - **General information** No special measures required.
  - **After inhalation** Supply fresh air; consult doctor in case of symptoms.
  - **After skin contact** Instantly wash with water and soap and rinse thoroughly.
  - **After eye contact** Rinse opened eye for several minutes under running water.
  - **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** -

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** No special measures required.
- **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.

(Contd. on page 3)



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

Printing date 27.01.2018

Version number 4

Revision: 27.01.2018

**Trade name: Signum cre-active**

(Contd. of page 2)

- **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**

- **Additional information about design of technical systems:** No further data; see item 7.

· **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/m3 (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.

· **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:** not absolutely necessary

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

IRL

(Contd. on page 4)



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

Printing date 27.01.2018

Version number 4

Revision: 27.01.2018

**Trade name: Signum cre-active**

(Contd. of page 3)

**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Viscous
      - **Colour:** According to product specification
    - **Smell:** Weak, characteristic
    - **Odour threshold:** Not determined.
  - **pH-value:** Not determined.
  - **Change in condition**
    - **Melting point/freezing point:** Not determined
    - **Initial boiling point and boiling range:** Not determined
  - **Flash point:** Not applicable
  - **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:**
    - **VOC EU** g/l
- **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

(Contd. on page 5)

IRL



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

Printing date 27.01.2018

Version number 4

Revision: 27.01.2018

**Trade name: Signum cre-active**

(Contd. of page 4)

· **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 toxicological effects**

· **Acute toxicity** Based on available data, the classification criteria are not met.

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

**1565-94-2 Bisphenol A-bis(hydroxypropylmethacrylate)**

Oral LD50 >5110 mg/kg (rat)

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

Oral LD50 > 5000 mg/kg (rat)

Dermal LD50 > 2000 mg/kg (mouse)

**75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide**

Oral LD50 > 5000 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)

**75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide**

EC50/48h 10 100 mg/l (algae)

10 - 100 mg/l (daphnia)

· **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.

· **Additional ecological information:**

· **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

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

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

(Contd. on page 6)



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

Printing date 27.01.2018

Version number 4

Revision: 27.01.2018

**Trade name: Signum cre-active**

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

(Contd. of page 5)

**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.

· **European waste catalogue**

18 01 06 chemicals consisting of or containing dangerous substances

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

**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

**SECTION 15: Regulatory information**

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **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.

H361f Suspected of damaging fertility.

(Contd. on page 7)





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

Printing date 27.01.2018

Version number 4

Revision: 27.01.2018

**Trade name: Signum cre-active**

(Contd. of page 6)

*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)*

*VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)*

*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*

*Repr. 2: Reproductive toxicity – Category 2*

*Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2*

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

IRL