



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

Printing date 15.09.2020

Version number 4

Revision: 11.08.2020

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

· **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**

P280 Wear protective gloves / eye protection.

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

· **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%

(Contd. on page 2)



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Trade name: Signum cre-active

(Contd. of page 1)		
CAS: 75980-60-8 EINECS: 278-355-8 Reg.nr.: 01-2119972295-29-xxxx	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f Aquatic Chronic 2, H411 Skin Sens. 1B, H317	≥0.25-<1%
CAS: 79-41-4 EINECS: 201-204-4 Reg.nr.: 01-2119463884-26-XXXX	methacrylic acid Acute Tox. 3, H311 Skin Corr. 1A, H314; Eye Dam. 1, H318 Acute Tox. 4, H302; Acute Tox. 4, H332; STOT SE 3, H335 Specific concentration limit: STOT SE 3; H335: C ≥ 1 %	≥0-<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.
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**
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.

(Contd. on page 3)



Safety data sheet
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Version number 4

Revision: 11.08.2020

Trade name: Signum cre-active

(Contd. of page 2)

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

- **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.
Not required.

· 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 necessary if room is well-ventilated.
 - **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 trough 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 15.09.2020

Version number 4

Revision: 11.08.2020

Trade name: Signum cre-active

(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:** 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.

· **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.

(Contd. on page 5)



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

Printing date 15.09.2020

Version number 4

Revision: 11.08.2020

Trade name: Signum cre-active

(Contd. of page 4)

- **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 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	>5,110 mg/kg (rat)
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109-16-0 triethylen glycol dimethacrylate

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

112945-52-5 Amorphous silica

Oral	LD50	>10,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)

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

Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)

79-41-4 methacrylic acid

Oral	LD50	1,320 mg/kg (rat) (OECD 401)
Dermal	LD50	500-1,000 mg/kg (rab)
Inhalative	LC50/4 h	7.1 mg/l (rat) (OECD 403)

- **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.

GB
(Contd. on page 6)



Safety data sheet
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Revision: 11.08.2020

Trade name: Signum cre-active

(Contd. of page 5)

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

109-16-0 triethylen glycol dimethacrylate

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

112945-52-5 Amorphous silica

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

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

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

10-100 mg/l (daphnia)

79-41-4 methacrylic acid

EC50/72h 45 mg/l (algae)

EC50/48h >130 mg/l (daphnia)

LC50/96h 85 mg/l (fish)

NOEC / 21d 53 mg/l (daphnia)

NOEC / 72h 8.2 mg/l (algae)

· **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.

· **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

(Contd. on page 7)



Safety data sheet
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Version number 4

Revision: 11.08.2020

Trade name: Signum cre-active

(Contd. of page 6)

· 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**

- H302 Harmful if swallowed.
- H311 Toxic in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H332 Harmful if inhaled.
- H335 May cause respiratory irritation.
- H361f Suspected of damaging fertility.
- 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

(Contd. on page 8)



Safety data sheet
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(Contd. of page 7)

PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity - oral – Category 4
Acute Tox. 3: Acute toxicity - dermal – Category 3
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
Repr. 2: Reproductive toxicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
*** Data compared to the previous version altered.**

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