



**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 01/27/2018

Reviewed on 01/27/2018

## 1 Identification

· **Product identifier**

· **Trade name: Signum cre-active**

· - colourfluids, transpafluids, gingiva

· **Application of the substance / the mixture** Auxiliary for manufacture of dental prothesis

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

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: [customer.servicehkna@kulzer-dental.com](mailto:customer.servicehkna@kulzer-dental.com)

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

## 2 Hazard(s) identification

· **Classification of the substance or mixture**

Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

Reproductive Toxicity - Category 2 H361 Suspected of damaging fertility or the unborn child.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

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

triethylen glycol dimethacrylate

diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

· **Hazard statements**

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wear protective gloves/protective clothing/eye protection/face protection.

If on skin: Wash with plenty of water.

Specific treatment (see on this label).

If skin irritation or rash occurs: Get medical advice/attention.

Store locked up.

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**



Health = 0

Fire = 1

Reactivity = 0

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· **HMIS-Ratings (Scale 0-4)**

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HEALTH	0	Health = 0
FIRE	1	Fire = 1
REACTIVITY	0	Reactivity = 0

· **Other hazards -**

### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
  - **Description:** Composition based on methacrylates
  - **Dangerous components:** Void
  - **Additional information** For the wording of the listed hazard phrases refer to section 16.

### 4 First-aid measures

- **Description of first aid measures**
  - **General information** No special measures required.
  - **After inhalation** Supply fresh air; consult doctor in case of complaints.
  - **After skin contact** Immediately 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.  
If symptoms persist consult doctor.
  - **Information for doctor**
    - **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
    - **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting measures

- **Extinguishing media**
  - **Suitable extinguishing agents**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
  - **Protective equipment:** No special measures required.
- **Additional information -**

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
- **Reference to other sections**  
No dangerous substances are released.  
See Section 8 for information on personal protection equipment.

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### 7 Handling and storage

- **Handling**
  - **Precautions for safe handling** No special measures required.
  - **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
  - **Storage**
    - **Requirements to be met by storerooms and receptacles:** No special requirements.
    - **Information about storage in one common storage facility:** Not required.
    - **Further information about storage conditions:** Keep cool, if possible (not above 25 °C).
  - **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
  - **Components with limit 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.
    - **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
  - **Personal protective equipment**
    - **General protective and hygienic measures**  
Wash hands before breaks and at the end of 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

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### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Viscous
      - **Color:** According to product specification
    - **Odor:** Weak, characteristic
    - **Odor threshold:** Not determined.
  - **pH-value:** Not determined.
  - **Change in condition**
    - **Melting point/Melting range:** undetermined
    - **Boiling point/Boiling range:** undetermined
  - **Flash point:** Not applicable
  - **Flammability (solid, gaseous)** Not applicable.
  - **Ignition temperature:**
    - **Decomposition temperature:** Not determined.
  - **Auto igniting:** Product is not selfigniting.
  - **Danger of explosion:** Product does not present an explosion hazard.
  - **Explosion limits:**
    - **Lower:** Not determined.
    - **Upper:** Not determined.
  - **Vapor pressure:** Not determined.
  - **Density:** Not determined
    - **Relative density** Not determined.
    - **Vapor 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.
  - **Other information** No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none
- **Additional information:**  
Product might polymerize after considerable exceeding of recommended storage time or temperature.

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**11 Toxicological information**

· **Information on toxicological effects**

· **Acute toxicity:**

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

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

Oral	LD50	>5110 mg/kg (rat)
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**109-16-0 triethylen glycol dimethacrylate**

Oral	LD50	> 5000 mg/kg (rat)
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Dermal	LD50	> 2000 mg/kg (mouse)
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**75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide**

Oral	LD50	> 5000 mg/kg (rat)
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· **Primary irritant effect:**

· **on the skin:** No irritant effect.

· **on the eye:** No irritating effect.

· **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

128-37-0	2,6-di-tert-butyl-p-cresol	3
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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

**12 Ecological information**

· **Toxicity**

· **Aquatic toxicity:**

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

EC50/72h	> 100 mg/l (algae)
Eigene Untersuchung von EVONIK	

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

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

· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

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

· **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 course or sewage system.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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

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**13 Disposal considerations**

· **Waste treatment methods**

· **Recommendation**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

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

**14 Transport information**

· **UN-Number**

· DOT, TDG, ADN, IMDG, IATA Void

· **UN proper shipping name**

· DOT, TDG, ADN, IMDG, IATA Void

· **Transport hazard class(es)**

· DOT, TDG, ADN, IMDG, IATA  
· Class Void

· **Packing group**

· DOT, TDG, IMDG, IATA Void

· **Environmental hazards:**

· **Marine pollutant:** No

· **Special precautions for user**

Not applicable.

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

· **Transport/Additional information:**

-

· **UN "Model Regulation":**

Void

**15 Regulatory information**

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

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

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triethylen glycol dimethacrylate  
diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide
- **Hazard statements**  
May cause an allergic skin reaction.  
Suspected of damaging fertility or the unborn child.
- **Precautionary statements**  
Avoid breathing dust/fume/gas/mist/vapours/spray.  
Wear protective gloves/protective clothing/eye protection/face protection.  
If on skin: Wash with plenty of water.  
Specific treatment (see on this label).  
If skin irritation or rash occurs: Get medical advice/attention.  
Store locked up.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 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.

· **Date of preparation / last revision** 01/27/2018 / 3

· **Abbreviations and acronyms:**

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

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

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