



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

Printing date 06/03/2017

Reviewed on 06/03/2017

## 1 Identification

· **Product identifier**

· **Trade name:** **PALA cre-active**  
**white, polar, pink, red, maroon, black, gum**

· **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.servicehna@kulzer-dental.com](mailto:customer.servicehna@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 Sens. 1 H317 May cause an allergic skin reaction.

Repr. 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

· **Hazard statements**

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

IF exposed or concerned: Get medical advice/attention.

Store locked up.

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· **Classification system**

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



· **HMIS-Ratings (Scale 0-4)**



· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**3 Composition/information on ingredients**

- **Chemical characterization: Substances**
  - **Identification number(s):** -
- **Chemical characterization: Mixtures**
  - **Description:** Composition based on methacrylates

· **Dangerous components:**

109-16-0	triethylen glycol dimethacrylate	Skin Sens. 1B, H317	25-50%
75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide	Repr. 2, H361	< 1%

**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.

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\* **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).  
Dispose of the collected material according to regulations.
- **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 disposal information.
- 

\* **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**

- **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.

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· **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:** Use safety goggles when grinding.

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

**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.

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· <b>Explosion limits:</b>	
· Lower:	Not determined.
· Upper:	Not determined.
· <b>Vapor pressure:</b>	Not determined.
· <b>Density:</b>	Not determined
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· <b>Solubility in / Miscibility with</b>	
· Water:	Not miscible or difficult to mix
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
· dynamic:	Not determined.
· kinematic:	Not determined.
· <b>Other information</b>	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.

**11 Toxicological information**

- **Information on toxicological effects**
- **Acute toxicity:**

· <b>LD/LC50 values that are relevant for classification:</b>	
<b>1565-94-2 Bisphenol A-bis(hydroxypropylmethacrylate)</b>	
Oral	LD50 >5110 mg/kg (rat)
<b>109-16-0 triethylen glycol dimethacrylate</b>	
Oral	LD50 > 5000 mg/kg (rat)
Dermal	LD50 > 2000 mg/kg (mouse)
<b>75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide</b>	
Oral	LD50 > 5000 mg/kg (rat)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.

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- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**  
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.  
The substance is not subject to classification according to the latest version of the EU lists.

- **Carcinogenic categories**

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

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

**12 Ecological information**

- **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)

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

**13 Disposal considerations**

- **Waste treatment methods**

- **Recommendation**

Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.

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- **Uncleaned packagings:**
  - **Recommendation:** Disposal must be made according to official regulations.
  - **Recommended cleansing agent:** Water, if necessary with cleansing agents.

**14 Transport information**

· <b>UN-Number</b>	
· DOT, ADR, ADN, IMDG, IATA	Void
· <b>UN proper shipping name</b>	
· DOT, ADR, ADN, IMDG, IATA	Void
· <b>Transport hazard class(es)</b>	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· <b>Packing group</b>	
· DOT, ADR, IMDG, IATA	Void
· <b>Environmental hazards:</b>	
· Marine pollutant:	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	-
· <b>UN "Model Regulation":</b>	Void

**15 Regulatory information**

· <b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>
· <b>SARA Section 355 (extremely hazardous substances)</b>
None of the ingredients is listed.
· <b>TSCA (Toxic Substances Control Act)</b> Medical devices are exempted from TSCA.
· <b>Cancerogenity categories</b>
· <b>TLV (Threshold Limit Value established by ACGIH)</b>
None of the ingredients is listed.
· <b>GHS label elements</b>
The product is classified and labeled according to the Globally Harmonized System (GHS).

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· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

· **Hazard-determining components of labeling:**  
triethylen glycol dimethacrylate

· **Hazard statements**

May cause an allergic skin reaction.  
Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray  
Wear protective gloves.  
Specific treatment (see on this label).  
Wash contaminated clothing before reuse.  
IF exposed or concerned: 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.

· **Relevant phrases**

H317 May cause an allergic skin reaction.  
H361 Suspected of damaging fertility or the unborn child.

· **Date of preparation / last revision** 06/03/2017 / 2

· **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  
DOT: US Department of Transportation  
IATA: International Air Transport Association  
ACGIH: American Conference of Governmental Industrial Hygienists  
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)  
NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
OSHA: Occupational Safety & Health  
TLV: Threshold Limit Value  
PEL: Permissible Exposure Limit  
REL: Recommended Exposure Limit  
Skin Sens. 1: Skin sensitisation – Category 1  
Skin Sens. 1B: Skin sensitisation – Category 1B

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*Repr. 2: Reproductive toxicity – Category 2*

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

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