



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

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

- **1.1 Product identifier**
 - Trade name: **PALA cre-active**
white, polar, pink, red, maroon, black, gum
- **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
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **Precautionary statements**
 - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 - P280 Wear protective gloves/protective clothing/eye protection/face protection.
 - P321 Specific treatment (see on this label).
 - P363 Wash contaminated clothing before reuse.
 - P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 - P302+P352 IF ON SKIN: Wash with plenty of water.
- **2.3 Other hazards -**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

- **3.1 Chemical characterisation: Substances**
 - **Identification number(s):** -
- **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%
CAS: 75980-60-8 EINECS: 278-355-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide ----- Repr. 2, H361f	< 1%

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**
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** 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).
Dispose of the material collected according to regulations.

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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.

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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

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

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- **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.
- **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

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/Melting range:**

Not determined

· **Boiling point/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.

· **Danger of explosion:**

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.

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· Evaporation rate	Not determined.
· Solubility in / Miscibility with · Water:	Not miscible or difficult to mix
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity: · dynamic: · kinematic:	Not determined. Not determined.
· 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:**
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.

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

SECTION 13: Disposal considerations

- **13.1 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.
 - **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.
 - **Recommended cleaning agent:** Water, if necessary with cleaning agent.

SECTION 14: Transport information

- **14.1 UN-Number**
 - **ADR, ADN, IMDG, IATA** Void
- **14.2 UN proper shipping name**
 - **ADR, ADN, IMDG, IATA** Void

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|--|-----------------|
| · 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.

· **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
- Repr. 2: Reproductive toxicity – Category 2

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