



**Safety Data Sheet
according to WHS Regulations**

Printing date 01.02.2021

Version number 4

Revision: 01.02.2021

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· **Product identifier**

· **Trade name: PALA cre-active Gingiva
clear, pink, light pink, R50, shade 200**

· **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

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

· **Manufacturer/Supplier:**
Kulzer Australia Pty Ltd
Unit 20, 53 Lorraine Street
Peakhurst, NSW 2210
Australia

Tel: +61 (0) 2 9153 0311

· **Informing department:** see above

· **Emergency telephone number:**

Poison Information Number: Australia 13 11 26 & New Zealand 0800 764 766

2 Hazard(s) Identification

· **Classification of the substance or mixture**

Acute Tox. 4 H332 Harmful if inhaled.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning

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

Kieselgel

1,12-dodecandioldimethacrylate

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

· **Hazard statements**

Harmful if inhaled.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

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

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

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

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If skin irritation or rash occurs: Get medical advice/attention.
Take off contaminated clothing and wash before reuse.

- **Other hazards -**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
 - **Description:** Product based on methacrylates

- **Dangerous components:**

| | | |
|--------------------------------------|--|--------|
| | Aliphatisches Polyestertriurethantriacrylat Skin Irrit. 2, H315; Eye Irrit. 2A, H319 | 10-25% |
| CAS: 72829-09-5 EINECS: 276-900-4 | 1,12-dodecandioldimethacrylate Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317; STOT SE 3, H335 | 5-10% |
| CAS: 24448-20-2 EINECS: 246-263-7 | 2-Propenoic acid,2-methyl-, 1,1'-[(1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanediyl)]ester Skin Irrit. 2, H315; Eye Irrit. 2A, H319 | 0-5% |
| CAS: 75980-60-8 EINECS: 278-355-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361; Skin Sens. 1B, H317 | < 1% |

- **Additional information** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **Description of first aid measures**
 - **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. If symptoms persist, consult doctor.
 - **After swallowing**
Rinse out mouth and then drink plenty of water.
In case of persistent symptoms 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**
CO₂, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **Advice for firefighters**
 - **Protective equipment:** Put on breathing apparatus.

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· **Additional information** -

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6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective clothing.
- **Environmental precautions:**
Do not allow product to reach sewage system or water bodies.
Do not allow to enter the ground/soil.
- **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.
- **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.

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 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).
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **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.
 - **Additional information:** The lists that were valid during the compilation were used as basis.
- **Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures**
Keep away from foodstuffs, beverages and food.
Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.
Avoid contact with the eyes and skin.
 - **Breathing equipment:** Not required.
 - **Protection of hands:**
If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.
Solvent resistant gloves
Check protective gloves prior to each use for their proper condition.

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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
- **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

- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.

· Solubility in / Miscibility with

- **Water:** Not miscible or difficult to mix

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- **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.
- **Chemical stability**
 - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **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:**
If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

11 Toxicological Information

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

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

| | | |
|---|----------|--------------------|
| 41137-60-4 diurethandimethacrylate | | |
| Oral | LD50 | >5000 mg/kg (rat) |
| 53879-55-3 penta erythritol, propoxylated, tetraacrylate | | |
| Oral | LD50 | >2000 mg/kg (rat) |
| 72829-09-5 1,12-dodecandioldimethacrylate | | |
| Oral | LD50 | >2000 mg/kg (rat) |
| Kieselgel | | |
| Oral | LD50 | >5000 mg/kg (rat) |
| Inhalative | LC50/4 h | >0.477 mg/l (rat) |
| 24448-20-2 2-Propenoic acid,2-methyl-, 1,1'-[(1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanediy)]ester | | |
| Oral | LD50 | >2000 mg/kg (rat) |
| 75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide | | |
| Oral | LD50 | > 5000 mg/kg (rat) |

- **Primary irritant effect:**
 - **Skin corrosion/irritation** Irritant for skin and mucous membranes.
 - **Serious eye damage/irritation** Irritant effect.
- **Respiratory or skin sensitisation** No sensitizing effect known.

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12 Ecological Information

· **Toxicity**

· **Aquatic toxicity:**

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.

· **Behaviour 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 product to reach ground water, water bodies or sewage system.

Danger to drinking water if even small quantities leak into soil.

· **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**

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**

· **ADG, ADN, IMDG, IATA**

Void

· **UN proper shipping name**

· **ADG, ADN, IMDG, IATA**

Void

· **Transport hazard class(es)**

· **ADG, ADN, IMDG, IATA**

· **Class**

Void

· **Packing group**

· **ADG, IMDG, IATA**

Void

· **Environmental hazards:**

· **Marine pollutant:**

No

· **Special precautions for user**

Not applicable.

· **Transport in bulk according to Annex II of
Marpol and the IBC Code**

Not applicable.

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- | | |
|--|------|
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
Kieselgel
1, 12-dodecandioldimethacrylate
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
- **Hazard statements**
Harmful if inhaled.
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
- **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Specific treatment (see on this label).
If skin irritation or rash occurs: Get medical advice/attention.
Take off contaminated clothing and wash before reuse.
- **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**
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H361 Suspected of damaging fertility or the unborn child.
- **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
EINECS: European Inventory of Existing Commercial Chemical Substances

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ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
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
· *** Data compared to the previous version altered.**

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