



**Safety Data Sheet  
according to WHS Regulations**

Printing date 17.07.2024

Version number 5

Revision: 17.07.2024

Hazardous according to criteria of Australian Safety and Compensation Council.

## 1 Identification

· **Product identifier**

· Trade name: **PALA cre-active gum**

· **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 St  
PEAKHURST NSW 2210  
Australia

Tel: +61 (02) 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**

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:**

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate  
1,12-Dodecanediol dimethacrylate  
triethylen glycol dimethacrylate

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid release to the environment.  
Wear protective gloves / eye protection.

· **Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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### 3 Composition and Information on Ingredients

· **Chemical characterisation: Mixtures**

· **Description: -**

· **Dangerous components:**

72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate Skin Sens. 1B, H317	≥10-≤25%
72829-09-5	1,12-Dodecanediol dimethacrylate Skin Sens. 1B, H317	≥1-≤10%
109-16-0	triethylen glycol dimethacrylate Skin Sens. 1B, H317	≥1-≤5%

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

### 4 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.  
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.
- **Information for doctor**
  - **Most important symptoms and effects, both acute and delayed** Allergic reactions
  - **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire Fighting Measures

- **Suitable extinguishing agents**  
CO<sub>2</sub>, 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.
- **Protective equipment:** No special measures required.
- **Additional information -**

### 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**  
Avoid contact with eyes and skin.
- **Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

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**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.
- Keep containers tightly sealed.
- Ensure good ventilation/exhaustion at the workplace.

**Information about protection against explosions and fires:** No special measures required.

**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:** None.

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

**8 Exposure controls and personal protection**

**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**

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate**

Oral	general population, long term, systemic	0.3 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	1.3 mg/Kg/d (not defined)
	general population, long term, systemic	0.7 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	3.3 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	0.6 mg/m <sup>3</sup> (not defined)

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

Oral	general population, long term, systemic	8.33 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.9 mg/Kg/d (not defined)
	general population, long term, systemic	8.33 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	48.5 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	14.5 mg/m <sup>3</sup> (not defined)

**PNECs**

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate**

freshwater	0.01 mg/l (not defined)
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marine water	0.001 mg/l (not defined)
sewage treatment plant	3.61 mg/l (not defined)
sediment, dry weight, freshwater	4.56 mg/Kg (not defined)
sediment, dry weight, marine water	0.46 mg/Kg (not defined)
soil, dry weight	0.91 mg/Kg (not defined)

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

freshwater	0.016 mg/l (not defined)
marine water	0.002 mg/l (not defined)
sewage treatment plant	1.7 mg/l (not defined)
sediment, dry weight, freshwater	0.185 mg/Kg (not defined)
sediment, dry weight, marine water	0.018 mg/Kg (not defined)
soil, dry weight	0.027 mg/Kg (not defined)

· **Additional information:** The lists that were valid during the compilation were used as basis.

· **Personal protective equipment**

· **General protective and hygienic measures**

Instantly remove any soiled and impregnated garments.  
Wash hands during breaks and at the end of the work.

· **Breathing equipment:** Not necessary if room is well-ventilated.

· **Protection of hands:**

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.  
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:** Tightly sealed safety glasses.

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

**9 Physical and Chemical Properties**

· **General Information**

· **Appearance:**

· **Form:**

Viscous

· **Colour:**

Brown

White

Pink

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- **Smell:** Weak, characteristic
- **Odour threshold:** Not determined.
- **pH-value:** Mixture is non-soluble (in water).
- **Change in condition**
- **Melting point/freezing point:** Not determined
- **Initial boiling point and boiling range:** 251 °C
- **Flash point:** >100 °C
- **Inflammability (solid, gaseous)** Not applicable.
- **Decomposition temperature:** Not determined.
- **Self-inflammability:** Product is not selfigniting.
- **Explosive properties:** Product is not explosive.  
Not determined.
- **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.
- **Other information** No further relevant information available.

**10 Stability and Reactivity**

- **Reactivity** No further relevant information available.
- **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:** -

**11 Toxicological Information**

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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

**112945-52-5 Amorphous silica**

Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
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Dermal	LD50	>5,000 mg/kg (rabbit)
<b>72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate</b>		
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)
<b>2530-85-0 3-trimethoxysilylpropyl methacrylate</b>		
Oral	LD50	>2,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)
<b>72829-09-5 1,12-Dodecanediol dimethacrylate</b>		
Oral	LD0	>2,000 mg/kg (rat) (OECD 423)
<b>109-16-0 triethylen glycol dimethacrylate</b>		
Oral	LD50	8,300 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (mouse)

- **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.
- **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.

**12 Ecological Information**

· **Toxicity**

· <b>Aquatic toxicity:</b>	
<b>112945-52-5 Amorphous silica</b>	
LC50/96h	>10,000 mg/l (fish) (OECD 203)
EC50 / 24h	>1,000 mg/l (daphnia)
<b>72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate</b>	
EC50/48h	>1.2 mg/l (daphnia) (OECD 202)
LC50/96h	10.1 mg/l (fish) (OECD 203)
ErC50 / 72 h	>0.68 mg/l (algae) (OECD 201)
NOEC / 72h	0.21 mg/l (algae) (OECD 201)
<b>2530-85-0 3-trimethoxysilylpropyl methacrylate</b>	
EC50/48h	>100 mg/l (daphnia) (EU C2.)
LC50/96h	>100 mg/l (fish) (EU C.1)
<b>109-16-0 triethylen glycol dimethacrylate</b>	
EC50/21d	51.9 mg/L (daphnia) (OECD 211)

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LC50/96h	16.4 mg/l (fish) (OECD 203)
NOEC / 21d	32 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>100 mg/l (algae) (OECD 201)
NOEC / 72h	18.6 mg/l (algae) (OECD 201)
EbC50 / 72h	72.8 mg/l (algae) (OECD 201)

**· Persistence and degradability**

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate**

Biodegradation 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

**2530-85-0 3-trimethoxysilylpropyl methacrylate**

Biodegradation 69 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

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

Biodegradation 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

**· 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 undiluted product or large quantities of it to reach ground water, water bodies 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**

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.

**· Uncleaned packagings:**

**· Recommendation:**

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

**14 Transport information**

**· UN-Number**

· **ADG, IMDG, IATA** UN3082

**· UN proper shipping name**

· **ADG** 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (7,7,9(or 7,9,9)-

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· <b>IMDG</b>	trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecane-1,16-diyl bismethacrylate, 1,12-Dodecanediol dimethacrylate)
· <b>IATA</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecane-1,16-diyl bismethacrylate, 1,12-Dodecanediol dimethacrylate), MARINE POLLUTANT
· <b>Transport hazard class(es)</b>	
· <b>ADG</b>	
	
· <b>Class</b>	9 (M6) Miscellaneous dangerous substances and articles.
· <b>Label</b>	9
· <b>IMDG, IATA</b>	
	
· <b>Class</b>	9 Miscellaneous dangerous substances and articles.
· <b>Label</b>	9
· <b>Packing group</b>	
· <b>ADG, IMDG, IATA</b>	III
· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>Special marking (ADG):</b>	Symbol (fish and tree)
· <b>Special marking (IATA):</b>	Symbol (fish and tree)
· <b>Special precautions for user</b>	Warning: Miscellaneous dangerous substances and articles.
· <b>Kemler Number:</b>	90
· <b>EMS Number:</b>	F-A,S-F
· <b>Stowage Category</b>	A
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	-

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<ul style="list-style-type: none"> <li>· <b>ADG</b></li> <li>· <b>Limited quantities (LQ)</b></li> <li>· <b>Excepted quantities (EQ)</b></li> <li>· <b>Transport category</b></li> <li>· <b>Tunnel restriction code</b></li> </ul>	<p>5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml 3 (-)</p>
<ul style="list-style-type: none"> <li>· <b>IMDG</b></li> <li>· <b>Limited quantities (LQ)</b></li> <li>· <b>Excepted quantities (EQ)</b></li> </ul>	<p>5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml</p>
<ul style="list-style-type: none"> <li>· <b>UN "Model Regulation":</b></li> </ul>	<p>UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (7,7,9(OR 7,9,9)-TRIMETHYL-4,13-DIOXO-3,14-DIOXA-5,12-DIAZAHEXADECANE-1,16-DIYL BISMETHACRYLATE, 1,12-DODECANEDIOL DIMETHACRYLATE), 9, III</p>

**15 Regulatory information**

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

<ul style="list-style-type: none"> <li>· <b>Australian Inventory of Industrial Chemicals</b></li> </ul>	
112945-52-5	Amorphous silica
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
2530-85-0	3-trimethoxysilylpropyl methacrylate
72829-09-5	1,12-Dodecanediol dimethacrylate
109-16-0	triethylen glycol dimethacrylate
102262-30-6	Silica (trimethylsilyl) oxy - modified
24650-42-8	2,2-dimethoxy-1,2-diphenylethan-1-one
64-19-7	acetic acid
1345-16-0	Cobalt zinc aluminate blue spinel
4948-15-6	C.I. Pigment Red 149
68186-88-9	Zinc iron chromite brown spinel
68186-91-4	Kupfer-, Chrom-, Eisenoxid-Spinell
13463-67-7	titanium dioxide
10373-78-1	dl-bornane-2,3-dione
80-62-6	methyl methacrylate
128-37-0	2,6-di-tert-butyl-p-cresol
7732-18-5	water, distilled, conductivity or of similar purity
77-99-6	propylidynetrimethanol

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· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **National regulations**

The product is subject to classification in accordance with the prevailing version of the regulations on hazardous materials.

· **Other regulations, limitations and prohibitive regulations**

· **AICS - Australian Inventory of Chemical Substances**

112945-52-5	Amorphous silica
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
2530-85-0	3-trimethoxysilylpropyl methacrylate
72829-09-5	1,12-Dodecanediol dimethacrylate
109-16-0	triethylen glycol dimethacrylate
102262-30-6	Silica (trimethylsilyl) oxy - modified
24650-42-8	2,2-dimethoxy-1,2-diphenylethan-1-one
64-19-7	acetic acid
1345-16-0	Cobalt zinc aluminate blue spinel
4948-15-6	C.I. Pigment Red 149
68186-88-9	Zinc iron chromite brown spinel
68186-91-4	Kupfer-, Chrom-, Eisenoxid-Spinell
	Chrome Antimony Titanate
13463-67-7	titanium dioxide
10373-78-1	dl-bornane-2,3-dione
80-62-6	methyl methacrylate
128-37-0	2,6-di-tert-butyl-p-cresol
7732-18-5	water, distilled, conductivity or of similar purity
	Diethyl-(2,5-dihydroxyterephthalat)
77-99-6	propylidynetrimehanol

· **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.

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

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

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