



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

Printing date 07/17/2024

Reviewed on 07/17/2024

## 1 Identification

· **Product identifier**

· Trade name: **PALA cre-active 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.servicehkna@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

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

## 2 Hazard(s) identification

· **Classification of the substance or mixture**

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **GHS label elements**

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

· **Hazard pictograms**



GHS07

· **Signal word** Warning

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

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-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.

· **Classification system**

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



Health = 0

Fire = 1

Reactivity = 0

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· **HMIS-Ratings (Scale 0-4)**

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

· **Results of PBT and vPvB assessment**

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

**3 Composition/information on ingredients**

· **Chemical characterization: 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	≥10-≤25%
	Sensitization - Skin 1B, H317	
72829-09-5	1,12-Dodecanediol dimethacrylate	≥1-≤10%
	Sensitization - Skin 1B, H317	
109-16-0	triethylen glycol dimethacrylate	≥1-≤5%
	Sensitization - Skin 1B, H317	

· **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 complaints.
- **After skin contact**  
Immediately 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 a doctor.
- **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** Allergic reactions
  - **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.

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- **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:** 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 seepage into sewage system, workpits and cellars.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
- **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.

· **Protective Action Criteria for Chemicals**

· <b>PAC-1:</b>		
112945-52-5	Amorphous silica	18 mg/m <sup>3</sup>
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	120 mg/m <sup>3</sup>
2530-85-0	3-trimethoxysilylpropyl methacrylate	71 mg/m <sup>3</sup>
109-16-0	triethylen glycol dimethacrylate	33 mg/m <sup>3</sup>
64-19-7	acetic acid	5 ppm
13463-67-7	titanium dioxide	30 mg/m <sup>3</sup>
80-62-6	methyl methacrylate	17 ppm

· <b>PAC-2:</b>		
112945-52-5	Amorphous silica	100 mg/m <sup>3</sup>
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	1,300 mg/m <sup>3</sup>
2530-85-0	3-trimethoxysilylpropyl methacrylate	780 mg/m <sup>3</sup>
109-16-0	triethylen glycol dimethacrylate	360 mg/m <sup>3</sup>
64-19-7	acetic acid	35 ppm
13463-67-7	titanium dioxide	330 mg/m <sup>3</sup>
80-62-6	methyl methacrylate	120 ppm

· <b>PAC-3:</b>		
112945-52-5	Amorphous silica	630 mg/m <sup>3</sup>
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	7,900 mg/m <sup>3</sup>
2530-85-0	3-trimethoxysilylpropyl methacrylate	4,700 mg/m <sup>3</sup>
109-16-0	triethylen glycol dimethacrylate	2,100 mg/m <sup>3</sup>
64-19-7	acetic acid	250 ppm

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13463-67-7	titanium dioxide	(Contd. of page 3) 2,000 mg/m <sup>3</sup>
80-62-6	methyl methacrylate	570 ppm

## 7 Handling and storage

- **Handling**
  - **Precautions for safe handling**  
No special measures required.  
Keep receptacles tightly sealed.  
Ensure good ventilation/exhaustion at the workplace.
  - **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:** None.
  - **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.  
Not required.
    - **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
  - **Personal protective equipment**
    - **General protective and hygienic measures**  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of 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.

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- **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 goggles.
- **Body protection:** Light weight protective clothing

### 9 Physical and chemical properties

#### · Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

##### · Form:

Viscous

##### · Color:

Brown

White

Pink

##### · Odor:

Weak, characteristic

##### · Odor threshold:

Not determined.

##### · pH-value:

Mixture is non-soluble (in water).

##### · Change in condition

##### · Melting point/Melting range:

undetermined

##### · Boiling point/Boiling range:

251 °C (483.8 °F)

##### · Flash point:

>100 °C (>212 °F)

##### · Flammability (solid, gaseous)

Not applicable.

##### · Decomposition temperature:

Not determined.

##### · Ignition temperature:

Product is not selfigniting.

##### · Danger of explosion:

Product does not present an explosion hazard.  
Not determined.

##### · 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.

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· **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:** -

**11 Toxicological information**

· **Information on toxicological effects**

· **Acute toxicity:**

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

**112945-52-5 Amorphous silica**

Oral LD50 >5,000 mg/kg (rat) (OECD 401)

Dermal LD50 >5,000 mg/kg (rabbit)

**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 LD50 >5,000 mg/kg (rat) (OECD 401)

Dermal LD50 >2,000 mg/kg (rat) (OECD 402)

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

Oral LD50 >2,000 mg/kg (rat)

Dermal LD50 >2,000 mg/kg (rabbit)

**72829-09-5 1,12-Dodecanediol dimethacrylate**

Oral LD0 >2,000 mg/kg (rat) (OECD 423)

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

Oral LD50 8,300 mg/kg (rat)

Dermal LD50 >2,000 mg/kg (mouse)

· **Sensitization:** Sensitization possible through skin contact.

· **Additional toxicological information:**

· **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.

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· **Reproductive toxicity** Based on available data, the classification criteria are not met.

**12 Ecological information**

· **Toxicity**

· **Aquatic toxicity:**

**112945-52-5 Amorphous silica**

LC50/96h >10,000 mg/l (fish) (OECD 203)

EC50 / 24h >1,000 mg/l (daphnia)

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

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)

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

EC50/48h >100 mg/l (daphnia) (EU C2.)

LC50/96h >100 mg/l (fish) (EU C.1)

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

EC50/21d 51.9 mg/L (daphnia) (OECD 211)

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-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate**

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

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

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

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

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

· **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.

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**

· DOT, ADR, IMDG, IATA

UN3082

· **UN proper shipping name**

· DOT

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)

· ADR

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)

· IMDG

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), MARINE POLLUTANT

· IATA

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)

· **Transport hazard class(es)**

· DOT, IMDG, IATA



· **Class**

9 Miscellaneous dangerous substances and articles

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· <b>Label</b>	9
· <b>ADR</b>	
· <b>Class</b>	9 (M6) Miscellaneous dangerous substances and articles
· <b>Label</b>	9
· <b>Packing group</b> · DOT, ADR, IMDG, IATA	III
· <b>Environmental hazards:</b> · Marine pollutant:	No Yes (DOT) Symbol (fish and tree)
· <b>Special marking (ADR):</b> · <b>Special marking (IATA):</b>	Symbol (fish and tree) Symbol (fish and tree)
· <b>Special precautions for user</b> · <b>Hazard identification number (Kemler code):</b> · <b>EMS Number:</b> · <b>Stowage Category</b>	Warning: Miscellaneous dangerous substances and articles 90 F-A,S-F A
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	-
· <b>DOT</b> · <b>Remarks:</b>	Special marking with the symbol (fish and tree).
· <b>ADR</b> · <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· <b>IMDG</b> · <b>Limited quantities (LQ)</b> · <b>Excepted quantities (EQ)</b>	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml

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· **UN "Model Regulation":**

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

**15 Regulatory information**

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.

· **Sara**

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

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

1345-16-0 Cobalt zinc aluminate blue spinel

80-62-6 methyl methacrylate

· **Hazardous Air Pollutants**

1345-16-0 Cobalt zinc aluminate blue spinel

80-62-6 methyl methacrylate

· **Proposition 65**

· **Prop 65 - Chemicals known to cause cancer**

13463-67-7 titanium dioxide

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

80-62-6 methyl methacrylate

E, NL

· **TLV (Threshold Limit Value)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

13463-67-7 titanium dioxide

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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### 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.

· **Date of preparation / last revision** 07/17/2024

· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Sensitization - Skin 1: Skin sensitisation – Category 1

Sensitization - Skin 1B: Skin sensitisation – Category 1B

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