



Safety Data Sheet
acc. to OSHA HCS

Printing date 07/29/2024

Reviewed on 07/29/2024

1 Identification

· **Product identifier**

· **Trade name:** Pala cre-active gingiva

· -

· **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.

Toxic to Reproduction 1B

H360 May damage fertility or the unborn child.

Specific Target Organ Toxicity - Repeated Exposure
2

H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· **Label elements**

· **GHS label elements**

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

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Danger

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

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

amorphe Kieselsäure, mit Sialamin oberflächenbehandelt

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

Hexamethylene diisocyanate, trimers, reactionproducts with 2-hydroxyethyl acrylate

1,12-Dodecanediol dimethacrylate

· **Hazard statements**

May cause an allergic skin reaction.

May damage fertility or the unborn child.

May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· **Precautionary statements**

Obtain special instructions before use.

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Avoid release to the environment.
Wear protective gloves / eye protection.
Wear protective clothing.
IF exposed or concerned: Get medical advice/attention.
Store locked up.

· **Additional information:**

9.1 % of the mixture consists of component(s) of unknown toxicity.

· **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: Mixtures**

· **Description:** Composition based on methacrylates

· **Dangerous components:**

72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Sensitization - Skin 1B, H317	≥50-≤75%
162492-01-5	Hexamethylene diisocyanate, trimers, reactionproducts with 2-hydroxyethyl acrylate Sensitization - Skin 1A, H317	≥10-≤25%
68909-20-6	amorphe Kieselsäure, mit Sialamin oberflächenbehandelt Specific Target Organ Toxicity - Repeated Exposure 2, H373	≥5-<10%
72829-09-5	1,12-Dodecanediol dimethacrylate Sensitization - Skin 1B, H317	≥1-≤10%
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Toxic to Reproduction 1B, H360 Sensitization - Skin 1B, H317	≥0.1-<1%

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

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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. If symptoms persist, 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**

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 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**

Formation of toxic gases is possible during heating or in case of fire.

· **Advice for firefighters**

· **Protective equipment:** Mount respiratory protective device.

· **Additional information -**

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**

Wear protective clothing.

Avoid contact with eyes and skin.

· **Environmental precautions:**

Do not allow product to reach sewage system or any water course.

Do not allow to penetrate 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 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.

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· Protective Action Criteria for Chemicals

· PAC-1:

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 ³
112945-52-5	Amorphous silica	18 mg/m ³
13463-67-7	titanium dioxide	30 mg/m ³
2530-85-0	3-trimethoxysilylpropyl methacrylate	71 mg/m ³
25322-68-3	polyethylene glycol	30 mg/m ³
64-19-7	acetic acid	5 ppm

· PAC-2:

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 ³
112945-52-5	Amorphous silica	100 mg/m ³
13463-67-7	titanium dioxide	330 mg/m ³
2530-85-0	3-trimethoxysilylpropyl methacrylate	780 mg/m ³
25322-68-3	polyethylene glycol	1,300 mg/m ³
64-19-7	acetic acid	35 ppm

· PAC-3:

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 ³
112945-52-5	Amorphous silica	630 mg/m ³
13463-67-7	titanium dioxide	2,000 mg/m ³
2530-85-0	3-trimethoxysilylpropyl methacrylate	4,700 mg/m ³
25322-68-3	polyethylene glycol	7,700 mg/m ³
64-19-7	acetic acid	250 ppm

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.

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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**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
 - **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.
Solvent resistant gloves
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:** Safety glasses
 - **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

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· Odor threshold:	Not determined.
· pH-value:	Mixture is non-soluble (in water).
· Change in condition	
· Melting point/Melting range:	undetermined
· Boiling point/Boiling range:	140 °C (284 °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.
· 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:**
Product might polymerize after considerable exceeding of recommended storage time or temperature.

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11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

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

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-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)

162492-01-5 Hexamethylene diisocyanate, trimers, reactionproducts with 2-hydroxyethyl acrylate

Oral LD50 5,000 mg/kg (rat) (OECD 423)

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

Aerosil R 812_ALT (siehe 66006689)

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

72829-09-5 1,12-Dodecanediol dimethacrylate

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

131-57-7 Oxybenzone

Oral LD50 >12,800 mg/kg (rat) (OECD 401)

Dermal LD50 >16,000 mg/kg (rabbit) (OECD 402)

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

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

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

· **Primary irritant effect:**

· **on the skin:** Irritant to skin and mucous membranes.

· **on the eye:** Irritating effect.

· **Sensitization:** No sensitizing effects known.

· **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.

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

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12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

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)

162492-01-5 Hexamethylene diisocyanate, trimers, reactionproducts with 2-hydroxyethyl acrylate

LL50/96h >100 mg/L (fish) (OECD 203)

EL50/48h >100 mg/L (daphnia) (OECD 202)

EL50/72h >100 mg/L (algae) (OECD 201)

NOELR 9.77 mg/L /72h (algae) (OECD 201)

≥100 mg/L /48h (daphnia) (OECD 202)

≥100 mg/L /96h (fish) (OECD 203)

131-57-7 Oxybenzone

EC50/48h 1.87 mg/l (daphnia) (OECD 202)

LC50/96h 3.8 mg/l (fish) (OECD 203)

ErC50 / 72 h 0.67 mg/l (algae) (OECD 201)

NOEC / 72h 0.18 mg/l (algae) (OECD 201)

NOEC / 96h 0.72 mg/l (fish) (OECD 203)

NOEC / 48h 1.15 mg/l (daphnia) (OECD 202)

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

EC50/48h 10,100 mg/l (algae)

3.53 mg/l (daphnia) (OECD 202)

LC50/96h 1.4 mg/l (fish) (OECD 203)

ErC50 / 72 h >2.01 mg/l (algae) (OECD 201)

ErC10/72h 1.56 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)

162492-01-5 Hexamethylene diisocyanate, trimers, reactionproducts with 2-hydroxyethyl acrylate

biodegradability 0 % /29d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

131-57-7 Oxybenzone

biodegradability 60-70 % /28d (not defined)

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75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

biodegradability 0-10 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

· **Behavior in environmental systems:**

· **Bioaccumulative potential**

131-57-7 Oxybenzone

Bloconcentration factor (BCF) >33-<160 (fish) (OECD 305)

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Bloconcentration factor (BCF) 47-55 (not defined)

· **Mobility in soil** No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.

· **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**

· **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)

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· 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
· Label	9

· ADR	
	
· Class	9 (M6) Miscellaneous dangerous substances and articles
· Label	9

· Packing group	III
· DOT, ADR, IMDG, IATA	

· Environmental hazards:	
· Marine pollutant:	No Yes (DOT) Symbol (fish and tree)
· Special marking (ADR):	Symbol (fish and tree)
· Special marking (IATA):	Symbol (fish and tree)

· Special precautions for user	Warning: Miscellaneous dangerous substances and articles
· Hazard identification number (Kemler code):	90
· EMS Number:	F-A,S-F

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· Stowage Category	A
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	-
· DOT	
· Remarks:	Special marking with the symbol (fish and tree).
· ADR	
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· IMDG	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· 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)**

None of the ingredients is listed.

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **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.

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

None of the ingredients is listed.

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **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.

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.

H360 May damage fertility or the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

· **Date of preparation / last revision** 07/29/2024

· **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 1A: Skin sensitisation – Category 1A

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

Toxic to Reproduction 1B: Reproductive toxicity – Category 1B

Specific Target Organ Toxicity - Repeated Exposure 2: Specific target organ toxicity (repeated exposure) – Category 2

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