



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: **Palaseal**

· **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**

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Dam. 1 H318 Causes serious eye damage.

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

Repr. 2 H361f Suspected of damaging fertility (causing atrophy of the testes).

STOT SE 3 H335 May cause respiratory irritation.

· **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**



GHS02 GHS05 GHS07 GHS08

· **Signal word** Danger

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

(2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate

methyl methacrylate

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

4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid

· **Hazard statements**

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H317 May cause an allergic skin reaction.

H361f Suspected of damaging fertility (causing atrophy of the testes).

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H335 May cause respiratory irritation.

· Precautionary statements

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

P241 Use explosion-proof electrical/ventilating/lighting/equipment.

P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P405 Store locked up.

· 2.3 Other hazards -

· Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

· **Description:** Product based on methacrylates

· Dangerous components:

CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-0000	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	25-50%
CAS: 40220-08-4 EINECS: 254-843-6	(2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate Eye Dam. 1, H318	25-50%
CAS: 55818-57-0 EINECS: 225-144-3 Reg.nr.: 01-2119490020-53-0001	4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid Skin Sens. 1, H317	5-10%
CAS: 52408-84-1 NLP: 500-114-5 Reg.nr.: 01-2119487948-12	glycerol, propoxylated, esters with acrylic acid Eye Irrit. 2, H319; Skin Sens. 1, H317	5-10%
CAS: 75980-60-8 EINECS: 278-355-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide Repr. 2, H361f	0-5%
	Polysiloxane hexaacrylate Acute Tox. 3, H331; Eye Irrit. 2, H319	< 1%

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

SECTION 4: First aid measures

· 4.1 Description of first aid measures

· **After inhalation** Supply fresh air; consult doctor in case of symptoms.

· **After skin contact**

Instantly rinse with water.

Seek medical treatment.

· **After eye contact**

Rinse opened eye for several minutes under running water.

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- Call a doctor immediately.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
Do not induce vomiting; instantly call for medical help.
- **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, sand, extinguishing powder. Do not use water.
 - **For safety reasons unsuitable extinguishing agents**
Water.
Water with a full water jet.
- **5.2 Special hazards arising from the substance or mixture**
Can form explosive gas-air mixtures.
Formation of toxic gases is possible during heating or in case of fire.
- **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**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
Do not flush with water or aqueous cleansing agents
- **6.4 Reference to other sections**
No dangerous materials are released.
See Section 8 for information on personal protection equipment.
-

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Please observe the additional instructions in the product's instructions for use.
Keep containers tightly sealed.
 - **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:** Store in cool location.
 - **Information about storage in one common storage facility:** Not required.

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- **Further information about storage conditions:**
Store cool (not above 25 °C).
Store in cool, dry conditions in well sealed containers.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

· **8.1 Control parameters**

- **Components with critical values that require monitoring at the workplace:**

80-62-6 methyl methacrylate

OES () Short-term value: 416 mg/m³, 100 ppm
Long-term value: 208 mg/m³, 50 ppm

· **DNELs**

80-62-6 methyl methacrylate

Dermal	worker industr., l.te., syst.	74.3 mg/Kg/d (human)
Inhalative	worker industr., l.te., syst.	210 mg/m ³ (human)

55818-57-0 4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid

Dermal	worker industr., l.te., syst.	17.5 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	122.5 mg/m ³ (nd)

52408-84-1 glycerol, propoxylated, esters with acrylic acid

Oral	worker profess., l.te., syst.	1.39 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	1.92 mg/Kg/d (nd)
	worker profess., l.te., syst.	1.15 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	16.2 mg/m ³ (nd)
	worker profess., l.te., syst.	4.87 mg/m ³ (nd)

· **PNECs**

80-62-6 methyl methacrylate

freshwater	0.94 mg/l (aqua)
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55818-57-0 4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid

freshwater	0.1 mg/l (nd)
marine water	0.01 mg/l (nd)
interm. wat. release	1.0 mg/l (nd)
STP	10 mg/l (nd)
sedim., dw, fre.wat.	35.8 mg/Kg (nd)
soil,dw	71 mg/Kg (nd)

52408-84-1 glycerol, propoxylated, esters with acrylic acid

freshwater	0.00574 mg/l (nd)
marine water	0.000574 mg/l (nd)

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interm. wat. release	0.0574 mg/l (nd)
STP	10 mg/l (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**

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 necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

· **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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:**

Protective goggles are recommended.
Tightly sealed safety glasses.

· **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:	Fluid
· Colour:	Yellow

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· Smell:	Characteristic
· Odour threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
· Melting point/Melting range:	Not determined
· Boiling point/Boiling range:	100 °C
· Flash point:	13 °C
· Inflammability (solid, gaseous)	Not applicable.
· Ignition temperature:	430 °C
· Decomposition temperature:	Not determined.
· Self-inflammability:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
· Critical values for explosion:	
· Lower:	2.1 Vol %
· Upper:	12.5 Vol %
· Steam pressure at 20 °C:	47 hPa
· Density at 20 °C	1.060 g/cm ³
· 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 at 20 °C:	11 mPas
· kinematic:	Not determined.
· Solvent content:	
· VOC EU	504.9 g/l
· Solids content:	32.6 %
· 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.

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- **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:**

80-62-6 methyl methacrylate

Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rab)
Inhalative	LC50/4 h	29.8 mg/l (rat)

55818-57-0 4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid

Oral	LD50	>5000 mg/kg (rat) (OECD 401)
Dermal	LD50	>5000 mg/kg (rabbit)
Sensitisation	Sensib.	(human) sensib. (mouse) (LLNA)

52408-84-1 glycerol, propoxylated, esters with acrylic acid

Oral	LD50	> 2000 mg/kg (rat)
Dermal	LD50	> 2000 mg/kg (rabbit)

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

Oral	LD50	> 5000 mg/kg (rat)
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Polysiloxane hexaacrylate

Oral	LD50	>2000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)
Inhalative	LC50/4 h	> 5 mg/l (rat)

- **Primary irritant effect:**
 - **Skin corrosion/irritation**
Causes skin irritation.
 - **Serious eye damage/irritation**
Causes serious eye damage.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - Repr. 2
 - **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**
Suspected of damaging fertility (causing atrophy of the testes).
- **STOT-single exposure**
May cause respiratory irritation.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.

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· **Aspiration hazard** Based on available data, the classification criteria are not met.

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

55818-57-0 4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid

EC50/72h > 110 mg/l (algae) (OECD 201)

LC50/96h > 79 mg/l (fish) (OECD 203)

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 product to reach ground water, water bodies or sewage system.

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

· **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**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Waste disposal key number:** 55512

· **European waste catalogue**

18 01 06 chemicals consisting of or containing dangerous substances

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, IMDG, IATA**

UN1247

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· 14.2 UN proper shipping name

· ADR

1247 METHYL METHACRYLATE MONOMER,
STABILIZED, solution

· IMDG, IATA

METHYL METHACRYLATE MONOMER,
STABILIZED, solution

· 14.3 Transport hazard class(es)

· ADR



· Class

3 (F1) Flammable liquids.

· Label

3

· IMDG, IATA



· Class

3 Flammable liquids.

· Label

3

· 14.4 Packing group

· ADR, IMDG, IATA

II

· 14.5 Environmental hazards:

· Marine pollutant:

No

· 14.6 Special precautions for user

· Kemler Number:

339

· EMS Number:

F-E, S-D

Warning: Flammable liquids.

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

Not applicable.

· Transport/Additional information:

-

· ADR

· Limited quantities (LQ)

1L

· Transport category

2

· Tunnel restriction code

D/E

· UN "Model Regulation":

UN1247, METHYL METHACRYLATE
MONOMER, STABILIZED, solution, 3, II

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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**

- H225 Highly flammable liquid and vapour.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H331 Toxic if inhaled.
- H335 May cause respiratory irritation.
- H361f Suspected of damaging fertility (causing atrophy of the testes).

· **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)
- VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
- 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
- Flam. Liq. 2: Flammable liquids – Category 2
- Acute Tox. 3: Acute toxicity – Category 3
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Dam. 1: Serious eye damage/eye irritation – Category 1
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- Skin Sens. 1: Skin sensitisation – Category 1
- Repr. 2: Reproductive toxicity – Category 2
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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