



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

1 Identification

· **Product identifier**

· **Trade name: Palaseal**

· **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)

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

2 Hazard(s) identification

· **Classification of the substance or mixture**

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

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 H361 Suspected of damaging fertility or the unborn child.

STOT SE 3 H335 May cause respiratory irritation.

· **Label elements**

· **GHS label elements**

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

· **Hazard pictograms**



GHS02 GHS05 GHS07 GHS08

· **Signal word** Danger

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

(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**

Highly flammable liquid and vapor.

Causes skin irritation.

Causes serious eye damage.

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

May cause respiratory irritation.

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· **Precautionary statements**

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

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

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor.

Store locked up.

· **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:**

80-62-6	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	25-50%
40220-08-4	(2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate Eye Dam. 1, H318	25-50%
55818-57-0	4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid Skin Sens. 1, H317	5-10%
52408-84-1	glycerol, propoxylated, esters with acrylic acid Eye Irrit. 2A, H319; Skin Sens. 1, H317	5-10%
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361	0-5%

· **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.

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- **After skin contact**
*Immediately rinse with water.
Seek medical treatment.*
- **After eye contact**
*Rinse opened eye for several minutes under running water.
Call a doctor immediately.*
- **After swallowing**
*Rinse out mouth and then drink plenty of water.
Do not induce vomiting; immediately call for medical help.*
- **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, sand, extinguishing powder. Do not use water.
 - **For safety reasons unsuitable extinguishing agents**
*Water.
Water with full jet.*
- **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.*
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **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).
Do not flush with water or aqueous cleansing agents*
- **Reference to other sections**
*No dangerous substances are released.
See Section 8 for information on personal protection equipment.*
-

7 Handling and storage

- **Handling**
 - **Precautions for safe handling**
*Please observe the additional instructions in the product's instructions for use.
Keep receptacles tightly sealed.*

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- **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and receptacles:** Store in a cool location.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:**
Keep cool, if possible (not above 25 °C).
Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

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

· **Components with limit values that require monitoring at the workplace:**

80-62-6 methyl methacrylate

PEL ()	410 mg/m ³ , 100 ppm
REL ()	410 mg/m ³ , 100 ppm
TLV ()	Short-term value: 410 mg/m ³ , 100 ppm Long-term value: 205 mg/m ³ , 50 ppm
SEN	

· **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 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

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

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

- **Form:** Fluid
- **Color:** Yellow
- **Odor:** Characteristic
- **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

- **Melting point/Melting range:** undetermined
- **Boiling point/Boiling range:** 100 °C (212 °F)

· **Flash point:** 13 °C (55 °F)

· **Flammability (solid, gaseous)** Not applicable.

· **Ignition temperature:** 430 °C (806 °F)

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

· **Explosion limits:**

- **Lower:** 2.1 Vol %
- **Upper:** 12.5 Vol %

· **Vapor pressure at 20 °C (68 °F):** 47 hPa (35 mm Hg)

· **Density at 20 °C (68 °F):** 1.060 g/cm³ (8.846 lbs/gal)

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

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· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· dynamic at 20 °C (68 °F):	11 mPas
· kinematic:	Not determined.
· Solvent content:	
· VOC USA	1020.0 g/l / 8.51 lb/gl
· Solids content:	32.6 %
· 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.

11 Toxicological information

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

· 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)
Sensitization	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:**
 - **on the skin:** Irritant to skin and mucous membranes.
 - **on the eye:** Strong irritant with the danger of severe eye injury.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant

· **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)		
80-62-6	methyl methacrylate	3

· NTP (National Toxicology Program)		
None of the ingredients is listed.		

· OSHA-Ca (Occupational Safety & Health Administration)		
None of the ingredients is listed.		

12 Ecological information

· **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)	

- **Persistence and degradability** No further relevant information available.
- **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 product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
- **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.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
· **DOT, ADR, IMDG, IATA** UN1247
- **UN proper shipping name**
· **ADR** 1247 METHYL METHACRYLATE MONOMER, STABILIZED, solution
· **IMDG, IATA** METHYL METHACRYLATE MONOMER, STABILIZED, solution
- **Transport hazard class(es)**
 - **DOT**
 3 Flammable liquids
· **Class** 3
· **Label**
 - **ADR**
 3 (F1) Flammable liquids
· **Class** 3
· **Label**
 - **IMDG, IATA**
 3 Flammable liquids
· **Class**

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· Label	3
· Packing group · DOT, ADR, IMDG, IATA	II
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user · Danger code (Kemler): · EMS Number:	Warning: Flammable liquids 339 F-E,S-D
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	-
· UN "Model Regulation":	UN1247, Methyl methacrylate monomer, stabilized, solution, 3, II

15 Regulatory information

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

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

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act)** Medical devices are exempted from TSCA.

· **Carcinogenicity categories**

· **TLV (Threshold Limit Value established by ACGIH)**

80-62-6 methyl methacrylate

A4

· **GHS label elements**

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

· **Hazard pictograms**



GHS02 GHS05 GHS07 GHS08

· **Signal word** Danger

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

(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**

Highly flammable liquid and vapor.

Causes skin irritation.

Causes serious eye damage.

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May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.
May cause respiratory irritation.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. No smoking.
Use explosion-proof electrical/ventilating/lighting/equipment.
If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER/doctor.
Store locked up.

· **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**

H225 Highly flammable liquid and vapor.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H361 Suspected of damaging fertility or the unborn child.

· **Date of preparation / last revision** 06/03/2017 / 2

· **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
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Flam. Liq. 2: Flammable liquids – Category 2
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
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.**