



**Safety data sheet  
according to 1907/2006/EC, Article 31**

Printing date 10.09.2020

Version number 4

Revision: 10.09.2020

**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](mailto: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.

STOT SE 3      H335    May cause respiratory irritation.

Aquatic Chronic 2   H411   Toxic to aquatic life with long lasting effects.

· **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   GHS09

· **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

Bisphenol A Diglycidylether Diacrylate (BADGE-DA)

glycerol, propoxylated, 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.

H335    May cause respiratory irritation.

H411    Toxic to aquatic life with long lasting effects.

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**Precautionary statements**

- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P261 Avoid breathing mist/vapours/spray.
- P273 Avoid release to the environment.
- P280 Wear protective gloves / eye protection.
- P309+P311 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.
- 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<br>EINECS: 201-297-1<br>Reg.nr.: 01-2119452498-28-XXXX    | methyl methacrylate<br>Flam. Liq. 2, H225<br>Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335                                    | ≥25-≤50% |
| CAS: 40220-08-4<br>EINECS: 254-843-6<br>Reg.nr.: 01-2120741502-64-xxxx | (2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate<br>Eye Dam. 1, H318<br>Aquatic Chronic 2, H411<br>Skin Sens. 1B, H317 | ≥25-≤50% |
| CAS: 55818-57-0<br>EINECS: 225-144-3<br>Reg.nr.: 01-2119490020-53-XXXX | Bisphenol A Diglycidylether Diacrylate (BADGE-DA)<br>Aquatic Chronic 2, H411<br>Skin Sens. 1, H317                                       | ≥5-≤10%  |
| CAS: 52408-84-1<br>NLP: 500-114-5<br>Reg.nr.: 01-2119487948-12         | glycerol, propoxylated, esters with acrylic acid<br>Eye Irrit. 2, H319; Skin Sens. 1, H317   | ≥5-≤10%  |
| CAS: 75980-60-8<br>EINECS: 278-355-8<br>Reg.nr.: 01-2119972295-29-xxxx | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide<br>Repr. 2, H361f<br>Aquatic Chronic 2, H411<br>Skin Sens. 1B, H317                      | ≥3-≤5%   |

· **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. Then consult doctor.
- **After swallowing**  
Rinse out mouth and then drink plenty of water.  
Do not induce vomiting; instantly call for medical help.

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- **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** CO<sub>2</sub>, sand, extinguishing powder. Do not use water.
  - **For safety reasons unsuitable extinguishing agents** Water.
- **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.  
Avoid contact with eyes and skin.
- **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** 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.
    - **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.

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**· 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/m<sup>3</sup>, 100 ppm  
Long-term value: 208 mg/m<sup>3</sup>, 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 <sup>3</sup> (human) |

**55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)**

|            |                               |                              |
|------------|-------------------------------|------------------------------|
| Dermal     | worker industr., l.te., syst. | 17.5 mg/Kg/d (nd)            |
| Inhalative | worker industr., l.te., syst. | 122.5 mg/m <sup>3</sup> (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 <sup>3</sup> (nd) |
|            | worker profess., l.te., syst. | 4.87 mg/m <sup>3</sup> (nd) |

**· PNECs**

**80-62-6 methyl methacrylate**

|            |                  |
|------------|------------------|
| freshwater | 0.94 mg/l (aqua) |
|------------|------------------|

**55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)**

|                      |                 |
|----------------------|-----------------|
| freshwater           | 0.1 mg/l (nd)   |
| marine water         | 0.01 mg/l (nd)  |
| interm. wat. release | 1 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) |
| 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).

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· **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:** 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

· **Smell:**

Characteristic

· **Odour threshold:**

Not determined.

· **pH-value:**

Not determined.

· **Change in condition**

· **Melting point/freezing point:**

Not determined

· **Initial boiling point and 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.

· **Explosive properties:**

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 %

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|  |  |
|--|--|
| · <b>Steam pressure at 20 °C:</b>                | 47 hPa                                     |
| · <b>Density at 20 °C</b>                        | 1.060 g/cm <sup>3</sup>                    |
| · <b>Relative density</b>                        | Not determined.                            |
| · <b>Vapour density</b>                          | Not determined.                            |
| · <b>Evaporation rate</b>                        | Not determined.                            |
| · <b>Solubility in / Miscibility with</b>        |  |
| · <b>Water:</b>                                  | Not miscible or difficult to mix           |
| · <b>Partition coefficient: n-octanol/water:</b> | Not determined.                            |
| · <b>Viscosity:</b>                              |  |
| · <b>dynamic at 20 °C:</b>                       | 11 mPas                                    |
| · <b>kinematic:</b>                              | Not determined.                            |
| · <b>Solvent content:</b>                        |  |
| · <b>VOC EU</b>                                  | 504.9 g/l                                  |
| · <b>9.2 Other information</b>                   | 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.
- **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.

| · <b>LD/LC50 values that are relevant for classification:</b>                        |          |                               |
|--|----------|-------------------------------|
| <b>80-62-6 methyl methacrylate</b>   |          |                               |
| Oral   | LD50     | ~7,900 mg/kg (rat)            |
| Dermal   | LD50     | >5,000 mg/kg (rab) (OECD 402) |
| Inhalative   | LC50/4 h | 29.8 mg/l (rat)               |
| <b>40220-08-4 (2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate</b> |          |                               |
| Oral   | LD50     | >2,000 mg/kg (rat) (OECD 423) |
| <b>55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)</b>                  |          |                               |
| Oral   | LD0      | >2,000 mg/kg (rat) (OECD 401) |
| Dermal   | LD0      | >2,000 mg/kg (rat) (OECD 402) |
| Sensitisation  | Sensib.  | (human)<br>(mouse) (LLNA)     |
| <b>52408-84-1 glycerol, propoxylated, esters with acrylic acid</b>                   |          |                               |
| Oral   | LD50     | >2,000 mg/kg (rat) (OECD 401) |

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|  |      |                                  |
|--|------|----------------------------------|
| Dermal   | LD50 | >2,000 mg/kg (rabbit) (OECD 402) |
| <b>75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide</b> |      |                                  |
| Oral   | LD50 | >5,000 mg/kg (rat) (OECD 401)    |
| Dermal   | LD50 | >2,000 mg/kg (rat) (OECD 402)    |

- **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.
- **STOT-single exposure**  
May cause respiratory irritation.
- **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.

**SECTION 12: Ecological information**

· **12.1 Toxicity**

|  |                                 |
|--|---------------------------------|
| · <b>Aquatic toxicity:</b>   |                                 |
| <b>80-62-6 methyl methacrylate</b>   |                                 |
| EC50/48h   | 69 mg/l (daphnia)               |
| LC50/96h   | 191 mg/l (fish)                 |
| <b>40220-08-4 (2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate</b> |                                 |
| EC50/48h   | 158.3 mg/l (daphnia) (OECD 202) |
| ErC50 / 72 h   | 25.7 mg/l (algae) (OECD 201)    |
| <b>55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)</b>                  |                                 |
| EC50/72h   | >110 mg/l (algae) (OECD 201)    |
| LC50/96h   | >79 mg/l (fish) (OECD 203)      |
| <b>75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide</b>                   |                                 |
| EC50/48h   | 10,100 mg/l (algae)             |
|  | 10-100 mg/l (daphnia)           |

· **12.2 Persistence and degradability**

|  |   |
|--|---|
| <b>40220-08-4 (2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate</b> |   |
| Biodegradation   | 32.2 % (nd) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D) |

· **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.

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- **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.

Disposal must be made according to official regulations.

· **Waste disposal key number:** 55512

· **European waste catalogue**

18 01 06\* chemicals consisting of or containing hazardous substances

· **Uncleaned packagings:**

· **Recommendation:**

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

**SECTION 14: Transport information**

· **14.1 UN-Number**

· **ADR, IMDG, IATA**

UN1247

· **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**



· **Class**

3 Flammable liquids.

· **Label**

3

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|   |  |
|---|--|
| · <b>IATA</b>   |  |
|  |  |
| · <b>Class</b>  | 3 Flammable liquids.   |
| · <b>Label</b>  | 3  |
| · <b>14.4 Packing group</b>   |  |
| · <b>ADR, IMDG, IATA</b>  | II   |
| · <b>14.5 Environmental hazards:</b>  |  |
| · <b>Marine pollutant:</b>  | No   |
|   | Symbol (fish and tree)   |
| · <b>Special marking (ADR):</b>   | Symbol (fish and tree)   |
| · <b>14.6 Special precautions for user</b>  | Warning: Flammable liquids.                                      |
| · <b>Kemler Number:</b>   | 339  |
| · <b>EMS Number:</b>  | F-E,S-D  |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>  | Not applicable.  |
| · <b>Transport/Additional information:</b>  | -  |
| · <b>ADR</b>  |  |
| · <b>Limited quantities (LQ)</b>  | 1L   |
| · <b>Transport category</b>   | 2  |
| · <b>Tunnel restriction code</b>  | D/E  |
| · <b>UN "Model Regulation":</b>   | UN1247, METHYL METHACRYLATE MONOMER, STABILIZED, solution, 3, II |

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - Directive 2012/18/EU
    - **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t
    - **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t
    - **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.
- H335 May cause respiratory irritation.

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*H361f Suspected of damaging fertility.*

*H411 Toxic to aquatic life with long lasting effects.*

**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

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

Skin Sens. 1B: Skin sensitisation – Category 1B

Repr. 2: Reproductive toxicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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

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