



**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 09/10/2020

Reviewed on 09/10/2020

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.servicehna@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 identification

· **Classification of the substance or mixture**

Flammable Liquids - Category 2

H225 Highly flammable liquid and vapour.

Skin Irritation - Category 2

H315 Causes skin irritation.

Serious Eye Damage - Category 1

H318 Causes serious eye damage.

Skin Sensitizer - Category 1

H317 May cause an allergic skin reaction.

Reproductive Toxicity - Category 2

H361 Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity - Single Exposure - Category 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

Bisphenol A Diglycidylether Diacrylate (BADGE-DA)

glycerol, propoxylated, esters with acrylic acid

· **Hazard statements**

Highly flammable liquid and vapour.

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.

· **Precautionary statements**

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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Avoid breathing mist/vapours/spray.
Avoid release to the environment.
Wear protective gloves / eye protection.
IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.
Store locked up.

· **Classification system**

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



Health = 2
Fire = 3
Reactivity = 2

· **HMIS-Ratings (Scale 0-4)**



Health = *3
Fire = 3
Reactivity = 2

· **Other hazards -**

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Composition based on methacrylates

· **Dangerous components:**

80-62-6	methyl methacrylate Flammable Liquids - Category 2, H225 Skin Irritation - Category 2, H315; Skin Sensitizer - Category 1, H317; Specific Target Organ Toxicity - Single Exposure - Category 3, H335	≥25-≤50% w/w *
40220-08-4	(2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate Serious Eye Damage - Category 1, H318 Skin Sensitizer - Category 1B, H317	≥25-≤50% w/w *
55818-57-0	Bisphenol A Diglycidylether Diacrylate (BADGE-DA) Skin Sensitizer - Category 1, H317	≥5-≤10% w/w *
52408-84-1	glycerol, propoxylated, esters with acrylic acid Eye Irritation - Category 2A, H319; Skin Sensitizer - Category 1, H317	≥5-<10% w/w *
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Reproductive Toxicity - Category 2, H361 Skin Sensitizer - Category 1B, H317	≥1-≤5% w/w *

* Actual concentration ranges are withheld as a trade secret.

· **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 rinse with water.

Seek medical treatment.

· **After eye contact**

Rinse opened eye for several minutes under running water. Then consult a doctor.

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- **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.
- **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.
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).
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** *Keep receptacles tightly sealed.*
 - **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.*

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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

EL () Short-term value: 125 ppm
Long-term value: 50 ppm
Skin, Z, A

· **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 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 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

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· 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 (55.4 °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 (35.3 mm Hg)
· Density at 20 °C (68 °F):	1.060 g/cm ³ (8.8457 lbs/gal)
· 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 at 20 °C (68 °F):	11 mPas
· kinematic:	Not determined.
· Solvent content:	
· VOC USA	1020.0 g/l / 8.51 lb/gl
· 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:**

80-62-6 methyl methacrylate

Oral	LD50	~7,900 mg/kg (rat) weight of evidence
Dermal	LD50	>5,000 mg/kg (rab) (OECD 402)
Inhalative	LC50/4 h	29.8 mg/l (rat)

40220-08-4 (2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate

Oral	LD50	>2,000 mg/kg (rat) (OECD 423)
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55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)

Oral	LD0	>2,000 mg/kg (rat) (OECD 401)
Dermal	LD0	>2,000 mg/kg (rat) (OECD 402)
Sensitization	Sensib.	(human) Haut sensibilisierend (mouse) (LLNA) LLNA (Local Lymph Node Assay)

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

Oral	LD50	>2,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 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:** 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
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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

80-62-6 methyl methacrylate

EC50/48h	69 mg/l (daphnia)
LC50/96h	191 mg/l (fish)

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40220-08-4 (2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate	
EC50/48h	158.3 mg/l (daphnia) (OECD 202)
ErC50 / 72 h	25.7 mg/l (algae) (OECD 201)
55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)	
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

40220-08-4 (2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate	
Biologischer Abbau	32.2 % (nd) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D) nach 54 d

· 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.
- **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/TDG, ADR, IMDG, IATA	UN1247
· UN proper shipping name	
· ADR	1247 METHYL METHACRYLATE MONOMER, STABILIZED, solution
· IMDG, IATA	METHYL METHACRYLATE MONOMER, STABILIZED, solution

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· **Transport hazard class(es)**

· **DOT/TDG (Transport dangerous goods):**



· **Class** 3 Flammable liquids
· **Label** 3

· **ADR**



· **Class** 3 (F1) Flammable liquids
· **Label** 3

· **IMDG**



· **Class** 3 Flammable liquids
· **Label** 3

· **IATA**



· **Class** 3 Flammable liquids
· **Label** 3

· **Packing group**

· **DOT/TDG, ADR, IMDG, IATA** II

· **Environmental hazards:**

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

· **Special precautions for user**

Warning: Flammable liquids

· **Hazard identification number (Kemler code):** 339
· **EMS Number:** F-E, S-D

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

· **Transport/Additional information:**

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· **DOT/TDG**

· **Remarks:**

Special marking with the symbol (fish and tree).

· **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

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

None of the ingredients is listed.

· **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 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.

H361 Suspected of damaging fertility or the unborn child.

· **Date of the latest revision of the safety data sheet** *09/10/2020 / 3*

· **Abbreviations and acronyms:**

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)

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

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