



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

Printing date 07/11/2022

Reviewed on 07/11/2022

1 Identification

· **Product identifier**

· **Trade name: PalaXpress powder**

· -

· **Application of the substance / the mixture** 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 identification

· **Classification of the substance or mixture**

Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **GHS label elements**

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

· **Hazard pictograms**



GHS07

· **Signal word** Warning

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

methyl methacrylate

dibenzoyl peroxide

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid release to the environment.

· **Classification system**

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



Health = 1

Fire = 1

Reactivity = 0

· **HMIS-Ratings (Scale 0-4)**



Health = 0

Fire = 1

Reactivity = 0

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· **Other hazards -**

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3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Product based on methacrylate copolymerisates

· **Dangerous components:**

72846-00-5	1-benzyl-5-phenylbarbituric acid Acute Toxicity (Oral) - Category 4, H302; Eye Irritation - Category 2A, H319	≥0-≤5% w/w *
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	≥0,1-<1% w/w *
94-36-0	dibenzoyl peroxide Organic Peroxides – Type B, H241 Eye Irritation - Category 2A, H319; Skin Sensitizer - Category 1, H317	≥0,1-<0,5% 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**

· **General information** No special measures required.

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

· **After skin contact** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact** Rinse opened eye for several minutes under running water.

· **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.

· **Special hazards arising from the substance or mixture** No further relevant information available.

· **Advice for firefighters**

· **Protective equipment:** No special measures required.

· **Additional information -**

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid contact with eyes and skin.
- **Environmental precautions:** Prevent seepage into sewage system, workpits and cellars.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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** 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.

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	STEL: 100 ppm TWA: 50 ppm S(D)
EV	STEL: 100 ppm TWA: 50 ppm
94-36-0 dibenzoyl peroxide	
EL	TWA: 5 mg/m ³
EV	TWA: 5 mg/m ³

· **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
 - **Breathing equipment:** Not necessary if room is well-ventilated.
 - **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
Check protective gloves prior to each use for their proper condition.
recommended

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- **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:** Powder
- **Color:** According to product specification
- **Odor:** Odorless
- **Odor threshold:** Not determined.

· **pH-value:** Not applicable.

· Change in condition

- **Melting point/Melting range:** undetermined
- **Boiling point/Boiling range:** undetermined

· **Flash point:** Not applicable

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

· **Decomposition temperature:** Not determined.

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

· **Danger of explosion:** Product is not explosive. However, formation of explosive powder/air mixture mis possible.

· Explosion limits:

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Vapor pressure:** Not applicable.

· Density:

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

· Solubility in / Miscibility with

· **Water:** Insoluble

· **Partition coefficient (n-octanol/water):** Not determined.

· Viscosity:

· **dynamic:** Not applicable.

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· kinematic:	Not applicable.
· Solvent content:	
· Solids content:	100,0 %
· 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

11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

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

72846-00-5 1-benzyl-5-phenylbarbituric acid

Oral	LD50	500 mg/kg (ATE) 500 mg/kg (rat) (OECD 423)
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80-62-6 methyl methacrylate

Oral	LD50	~7.900 mg/kg (rat) weight of evidence
Dermal	LD50	>5.000 mg/kg (guinea pig) (OECD 402)
Inhalative	LC50/4 h	29,8 mg/l (rat)

94-36-0 dibenzoyl peroxide

Oral	LD0	>2.000 mg/kg (mouse) (OECD 401)
Inhalative	LC0/4h	24,3 ppm (rat) (OECD 403)

· **Primary irritant effect:**

- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.

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

· **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **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.

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

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12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

72846-00-5 1-benzyl-5-phenylbarbituric acid

EC50/48h >50 mg/l (daphnia) (OECD 202)

ErC50 / 72 h >50 mg/l (algae) (OECD 201)

80-62-6 methyl methacrylate

EC50/21d 49 mg/L (daphnia) (OECD 211)

EC50/48h 69 mg/l (daphnia) (EPA OTS 797.1300)

NOEC / 21d 37 mg/l (daphnia) (OECD 211)

ErC50 / 72 h >110 mg/l (algae) (OECD 201)

NOEC / 72h 110 mg/l (algae) (OECD 201)

NOEC / 48h 48 mg/l (daphnia) (EPA OTS 797.1300)

EbC50 / 72h >110 mg/l (algae) (OECD 201)

NOEC/ 35d 9,4 mg/L (fish) (OECD 210)

LC50/ 35d 33,7 mg/L (fish) (OECD 210)

94-36-0 dibenzoyl peroxide

EC50/72h 0,042 mg/l (algae) (OECD 201)

EC50/48h 0,11 mg/l (daphnia) (OECD 202)

LC50/96h 0,06 mg/l (fish) (OECD 203)

ErC50 / 72 h 0,071 mg/l (algae) (OECD 201)

NOEC / 72h 0,02 mg/l (algae) (OECD 201)

NOEC / 96h 0,032 mg/l (fish) (OECD 203)

NOEC / 48h 0,076 mg/l (daphnia) (OECD 202)

ErC10 0,001 mg/L /21d (daphnia) (OECD 211)

· **Persistence and degradability**

72846-00-5 1-benzyl-5-phenylbarbituric acid

biodegradability 29,1 % /29d (not defined) (OECD 301D)

80-62-6 methyl methacrylate

biodegradability 94 % /14d (not defined) (OECD 301C)

94-36-0 dibenzoyl peroxide

biodegradability 71 % /28d (not defined) (OECD 301D)

· **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 undiluted product or large quantities of it to reach ground water, water course or sewage system.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **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.

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**

Void

UN3077

· **UN proper shipping name**

· **DOT/TDG**

· **ADR**

· **IMDG**

· **IATA**

Void

3077 Environmentally hazardous substance, solid, n.o.s. (dibenzoyl peroxide)

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide), MARINE POLLUTANT

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)

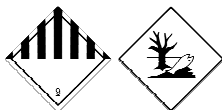
· **Transport hazard class(es)**

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

· **Class**

Void

· **ADR**



· **Class**

9 (M7) Miscellaneous dangerous substances and articles

· **Label**

9

· **IMDG, IATA**



· **Class**

9 Miscellaneous dangerous substances and articles

· **Label**

9

· **Packing group**

· **DOT/TDG**

Void

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· ADR, IMDG, IATA	III
· Environmental hazards:	
· Marine pollutant:	No 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
· Stowage Category	A
· Stowage Code	SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	-
· ADR	
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· IMDG	
· Limited quantities (LQ)	5 kg
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· UN "Model Regulation":	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (DIBENZOYL PEROXIDE), 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.

· **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.
- H241 Heating may cause a fire or explosion.
- H302 Harmful if swallowed.

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H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

· **Date of the latest revision of the safety data sheet 07/11/2022 / 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)

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.**

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