



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

Printing date 11.07.2022

Version number 4 (replaces version 3)

Revision: 11.07.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking

· **1.1 Product identifier**

· Trade name: **PalaXpress powder**

· **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 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

Aquatic Chronic 2 H411 (M=10) 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 GB CLP regulation.

· Hazard pictograms



GHS09

· Signal word Void

· Hazard statements

H411 Toxic to aquatic life with long lasting effects.

· Precautionary statements

P273 Avoid release to the environment.

· Additional information:

Contains methyl methacrylate, dibenzoyl peroxide. May produce an allergic reaction.

· **2.3 Other hazards -**

· Results of PBT and vPvB assessment

· PBT: Not applicable.

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· Description: Product based on methacrylate copolymers

· Dangerous components:

CAS: 72846-00-5 EINECS: 276-940-2	1-benzyl-5-phenylbarbituric acid Acute Tox. 4, H302; Eye Irrit. 2, H319 ATE: LD50 oral: 500 mg/kg	≥0-≤5%
CAS: 80-62-6 EINECS: 201-297-1	methyl methacrylate Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	≥0.1-<1%

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Trade name: PalaXpress powder

CAS: 94-36-0
EINECS: 202-327-6

dibenzoyl peroxide
Self-react. B, H241; Org. Perox. B, H241
Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=10)
Eye Irrit. 2, H319; Skin Sens. 1, H317

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≥0.25-<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**
 - **General information** No special measures required.
 - **After inhalation** Supply fresh air; consult doctor in case of symptoms.
 - **After skin contact** Instantly 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.
In case of persistent symptoms consult doctor.
- **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, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
- **5.2 Special hazards arising from the substance or mixture**
No further relevant information available.
- **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**
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:** Collect mechanically.
- **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** No special measures required.
 - **Information about protection against explosions and fires:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** Store cool (not above 25 °C).

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· 7.3 Specific end use(s) No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· Components with critical values that require monitoring at the workplace:

80-62-6 methyl methacrylate

WEL (Great Britain)	Short-term value: 416 mg/m ³ , 100 ppm Long-term value: 208 mg/m ³ , 50 ppm
IOELV (European Union)	Short-term value: 100 ppm Long-term value: 50 ppm

94-36-0 dibenzoyl peroxide

WEL (Great Britain)	Long-term value: 5 mg/m ³
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· DNELs

80-62-6 methyl methacrylate

Oral	general population, long term, systemic	8.2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.67 mg/Kg/d (not defined)
Inhalative	general population, long term, systemic	8.2 mg/Kg/d (not defined)
	worker industrial, acute, local	416 mg/m ³ (not defined)
	worker industrial, long term, systemic	348.4 mg/m ³ (not defined)
	worker industrial, long term, local	208 mg/m ³ (not defined)
	general population, acute, local	208 mg/m ³ (not defined)
	general population, long term, systemic	74.3 mg/m ³ (not defined)

94-36-0 dibenzoyl peroxide

Oral	general population, long term, systemic	2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.3 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	39 mg/m ³ (not defined)

· PNECs

80-62-6 methyl methacrylate

freshwater	0.94 mg/l (not defined)
marine water	0.094 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	10.2 mg/Kg (not defined)
sediment, dry weight, marine water	0.102 mg/Kg (not defined)
soil, dry weight	1.48 mg/Kg (not defined)

94-36-0 dibenzoyl peroxide

freshwater	0.00002 mg/l (not defined)
marine water	0.000002 mg/l (not defined)
sewage treatment plant	0.35 mg/l (not defined)
sediment, dry weight, freshwater	0.013 mg/Kg (not defined)
sediment, dry weight, marine water	0.001 mg/Kg (not defined)
soil, dry weight	0.003 mg/Kg (not defined)

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

· 8.2 Exposure controls

· Appropriate engineering controls No further data; see item 7.

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· **Individual protection measures, such as personal protective equipment**

· **General protective and hygienic measures**

The usual precautionary measures should be adhered to in handling the chemicals.

· **Breathing equipment:** Not necessary if room is well-ventilated.

· **Hand protection**

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

· **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/face protection** 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**

· **Physical state**

Solid.

· **Colour:**

According to product specification

· **Smell:**

Odourless

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Not determined

· **Boiling point or initial boiling point and boiling range**

Not determined

· **Flammability**

Not determined.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

Not applicable

· **Decomposition temperature:**

Not determined.

· **SADT**

· **pH**

Not applicable.

· **Viscosity:**

· **Kinematic viscosity**

Not applicable.

· **dynamic:**

Not applicable.

· **Solubility**

· **Water:**

Insoluble

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Steam pressure:**

Not applicable.

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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)
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)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **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.

11.2 Information on other hazards

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

12.1 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)

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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)

· **12.2 Persistence and degradability**

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

Biodegradation 29.1 % /29d (not defined) (OECD 301D)

80-62-6 methyl methacrylate

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

94-36-0 dibenzoyl peroxide

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

· **12.3 Bioaccumulative potential** No further relevant information available.

· **12.4 Mobility in soil** No further relevant information available.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Endocrine disrupting properties**

For information on endocrine disrupting properties see section 11.

· **12.7 Other adverse effects**

· **Additional ecological information:**

· **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

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.

· **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 or ID number**

· **ADR, IMDG, IATA**

UN3077

· **14.2 UN proper shipping name**

· **ADR**

3077 ENVIRONMENTALLY HAZARDOUS
SUBSTANCE, SOLID, N.O.S. (dibenzoyl
peroxide)

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· IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide), MARINE POLLUTANT
· IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)
· 14.3 Transport hazard class(es)	
· ADR	
· Class	9 (M7) Miscellaneous dangerous substances and articles.
· Label	9
· IMDG, IATA	
· Class	9 Miscellaneous dangerous substances and articles.
· Label	9
· 14.4 Packing group	
· ADR, IMDG, IATA	III
· 14.5 Environmental hazards:	
· Marine pollutant:	No Symbol (fish and tree)
· Special marking (ADR):	Symbol (fish and tree)
· Special marking (IATA):	Symbol (fish and tree)
· 14.6 Special precautions for user	Warning: Miscellaneous dangerous substances and articles.
· Kemler Number:	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.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	-
· ADR	
· 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
· Transport category	3

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· Tunnel restriction code	(-)
· 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

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** 200 t
 - **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **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.
- H241 Heating may cause a fire or explosion.
- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

· **Abbreviations and acronyms:**

- SADT: Self Accelerating Decomposition Temperature
- ADR: Accord relatif au transport international 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)
- DNEL: Derived No-Effect Level (UK REACH)
- PNEC: Predicted No-Effect Concentration (UK 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
- Self-react. B: Self-reactive substances and mixtures – Type B
- Org. Perox. B: Organic peroxides – Type B
- Acute Tox. 4: Acute toxicity – Category 4
- Skin Irrit. 2: Skin corrosion/irritation – Category 2

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Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

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

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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

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

GB