



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

Printing date 14.07.2022

Version number 2 (replaces version 1)

Revision: 14.07.2022

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

- **1.1 Product identifier**
  - Trade name: **PalaXtreme 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](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**  
Aquatic Chronic 3 H412 (M=10) Harmful 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** Void
    - **Signal word** Void
    - **Hazard statements**  
H412 Harmful to aquatic life with long lasting effects.
    - **Precautionary statements**  
P273 Avoid release to the environment.
  - **Additional information:**  
Contains methyl methacrylate, 2-ethylhexyl thioglycolate, 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:** -

· **Dangerous components:**

CAS: 72846-00-5 EINECS: 276-940-2 Reg.nr.: 01-2120226211-75-XXXX	1-benzyl-5-phenylbarbituric acid Acute Tox. 4, H302; Eye Irrit. 2, H319	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%
CAS: 7659-86-1 EINECS: 231-626-4	2-ethylhexyl thioglycolate Aquatic Acute 1, H400; Aquatic Chronic 1, H410 Acute Tox. 4, H302; Skin Sens. 1B, H317 ATE: LD50 oral: 303 mg/kg	≥0.25-<1%

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**Trade name: PalaXtreme 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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≥0.1-<0.25%

#### **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**  
CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.  
Use fire fighting measures that suit the environment.
- **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** Not required.
- **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**  
See Section 7 for information on safe handling  
See Section 8 for information on personal protection equipment.  
See Section 13 for information on disposal.  
-

#### **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.

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- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

**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**

OEL (Ireland)	Short-term value: 100 ppm Long-term value: 50 ppm IOELV, Sens
IOELV (European Union)	Short-term value: 100 ppm Long-term value: 50 ppm

**94-36-0 dibenzoyl peroxide**

OEL (Ireland)	Long-term value: 5 mg/m <sup>3</sup> Sens
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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)
	general population, long term, systemic	8.2 mg/Kg/d (not defined)
Inhalative	worker industrial, acute, local	416 mg/m <sup>3</sup> (not defined)
	worker industrial, long term, systemic	348.4 mg/m <sup>3</sup> (not defined)
	worker industrial, long term, local	208 mg/m <sup>3</sup> (not defined)
	general population, acute, local	208 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	74.3 mg/m <sup>3</sup> (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 <sup>3</sup> (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)

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· **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.

· **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.

· **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:**

White

· **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

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- |  |                 |
|--|-----------------|
| · <b>Partition coefficient n-octanol/water (log value)</b> | Not determined. |
| · <b>Steam pressure:</b>                                   | Not applicable. |
| · <b>Density and/or relative density</b>                   |                 |
| · <b>Density</b>   | Not determined  |
| · <b>Relative density</b>                                  | Not determined. |
| · <b>Vapour density</b>                                    | Not applicable. |
| · <b>Particle characteristics</b>                          | See item 3.     |

- |  |  |
|--|--|
| · <b>9.2 Other information</b>   | No further relevant information available.   |
| · <b>Appearance:</b>   |  |
| · <b>Form:</b>   | Powder                                       |
| · <b>Important information on protection of health and environment, and on safety.</b> |  |
| · <b>Self-inflammability:</b>  | Product is not selfigniting.                 |
| · <b>Explosive properties:</b>   | Product is not explosive.<br>Not determined. |
| · <b>Change in condition</b>   |  |
| · <b>Evaporation rate</b>  | Not applicable.                              |

- |  |      |
|--|------|
| · <b>Information with regard to physical hazard classes</b>                        |      |
| · <b>Explosives</b>  | Void |
| · <b>Flammable gases</b>   | Void |
| · <b>Aerosols</b>  | Void |
| · <b>Oxidising gases</b>   | Void |
| · <b>Gases under pressure</b>  | Void |
| · <b>Flammable liquids</b>   | Void |
| · <b>Flammable solids</b>  | Void |
| · <b>Self-reactive substances and mixtures</b>                                     | Void |
| · <b>Pyrophoric liquids</b>  | Void |
| · <b>Pyrophoric solids</b>   | Void |
| · <b>Self-heating substances and mixtures</b>                                      | Void |
| · <b>Substances and mixtures, which emit flammable gases in contact with water</b> | Void |
| · <b>Oxidising liquids</b>   | Void |
| · <b>Oxidising solids</b>  | Void |
| · <b>Organic peroxides</b>   | Void |
| · <b>Corrosive to metals</b>   | Void |
| · <b>Desensitised explosives</b>   | Void |

**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:** -

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**SECTION 11: Toxicological information**

**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

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

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

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

Oral	LD50	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)

**7659-86-1 2-ethylhexyl thioglycolate**

Oral	LD50	303 mg/kg (ATE) 303 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)

**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:**

**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)

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**7659-86-1 2-ethylhexyl thioglycolate**

EC50/48h	0.39 mg/l (daphnia) (OECD 202)
ErC50 / 72 h	0.62 mg/l (algae) (OECD 201)
ErC10/72h	0.42 mg/L (algae) (OECD 201)

**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)

**12.2 Persistence and degradability**

**80-62-6 methyl methacrylate**

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

**7659-86-1 2-ethylhexyl thioglycolate**

Biodegradation 82 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

**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:** Avoid transfer into the environment.

**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.

· **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.

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**SECTION 14: Transport information**

· 14.1 UN number or ID number · ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	-
· UN "Model Regulation":	Void

**SECTION 15: Regulatory information**

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Directive 2012/18/EU
  - Named dangerous substances - ANNEX I None of the ingredients is listed.
- 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.

· **Date of previous version:** 24.05.2022

· **Version number of previous version:** 1

· **Abbreviations and acronyms:**

- RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
- IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
- ICAO: International Civil Aviation Organisation
- ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

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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 (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  
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  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
Skin Sens. 1: Skin sensitisation – Category 1  
Skin Sens. 1B: Skin sensitisation – Category 1B  
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 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3  
\* **Data compared to the previous version altered.**

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