



**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 GB 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<br>EINECS: 276-940-2<br>Reg.nr.: 01-2120226211-75-XXXX | 1-benzyl-5-phenylbarbituric acid<br>Acute Tox. 4, H302; Eye Irrit. 2, H319   | 0-5%      |
| CAS: 80-62-6<br>EINECS: 201-297-1                                      | methyl methacrylate<br>Flam. Liq. 2, H225<br>Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335  | ≥0.1-<1%  |
| CAS: 7659-86-1<br>EINECS: 231-626-4                                    | 2-ethylhexyl thioglycolate<br>Aquatic Acute 1, H400; Aquatic Chronic 1, H410<br>Acute Tox. 4, H302; Skin Sens. 1B, H317<br>ATE: LD50 oral: 303 mg/kg | ≥0.25-<1% |

(Contd. on page 2)



**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

**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

(Contd. of page 1)  
≥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.

(Contd. on page 3)



**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

**Trade name: PalaXtreme Powder**

(Contd. of page 2)

- **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**

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

**94-36-0 dibenzoyl peroxide**

|                     |                                      |
|---------------------|--------------------------------------|
| WEL (Great Britain) | Long-term value: 5 mg/m <sup>3</sup> |
|---------------------|--------------------------------------|

· **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 <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)   |

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

(Contd. on page 4)



**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

**Trade name: PalaXtreme Powder**

(Contd. of page 3)

**· 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

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

Not determined.

(Contd. on page 5)



**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

**Trade name: PalaXtreme Powder**

(Contd. of page 4)

|   |  |
|---|--|
| <ul style="list-style-type: none"> <li>· <b>Steam pressure:</b> Not applicable.</li> <li>· <b>Density and/or relative density</b> <ul style="list-style-type: none"> <li>· <b>Density</b> Not determined</li> <li>· <b>Relative density</b> Not determined.</li> <li>· <b>Vapour density</b> Not applicable.</li> </ul> </li> </ul>   |  |
| <ul style="list-style-type: none"> <li>· <b>9.2 Other information</b> No further relevant information available.</li> <li>· <b>Appearance:</b> <ul style="list-style-type: none"> <li>· <b>Form:</b> Powder</li> </ul> </li> <li>· <b>Important information on protection of health and environment, and on safety.</b> <ul style="list-style-type: none"> <li>· <b>Self-inflammability:</b> Product is not selfigniting.</li> <li>· <b>Explosive properties:</b> Product is not explosive.<br/>Not determined.</li> </ul> </li> <li>· <b>Change in condition</b> <ul style="list-style-type: none"> <li>· <b>Evaporation rate</b> Not applicable.</li> </ul> </li> </ul>   |  |
| <ul style="list-style-type: none"> <li>· <b>Information with regard to physical hazard classes</b> <ul style="list-style-type: none"> <li>· <b>Explosives</b> Void</li> <li>· <b>Flammable gases</b> Void</li> <li>· <b>Aerosols</b> Void</li> <li>· <b>Oxidising gases</b> Void</li> <li>· <b>Gases under pressure</b> Void</li> <li>· <b>Flammable liquids</b> Void</li> <li>· <b>Flammable solids</b> Void</li> <li>· <b>Self-reactive substances and mixtures</b> Void</li> <li>· <b>Pyrophoric liquids</b> Void</li> <li>· <b>Pyrophoric solids</b> Void</li> <li>· <b>Self-heating substances and mixtures</b> Void</li> <li>· <b>Substances and mixtures, which emit flammable gases in contact with water</b> Void</li> <li>· <b>Oxidising liquids</b> Void</li> <li>· <b>Oxidising solids</b> Void</li> <li>· <b>Organic peroxides</b> Void</li> <li>· <b>Corrosive to metals</b> Void</li> <li>· <b>Desensitised explosives</b> Void</li> </ul> </li> </ul> |  |

**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:** -

**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.

(Contd. on page 6)



**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

**Trade name: PalaXtreme Powder**

(Contd. of page 5)

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

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

Oral LD50 500 mg/kg (rat) (OECD 423)

**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)

**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)

(Contd. on page 7)



**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

**Trade name: PalaXtreme Powder**

(Contd. of page 6)

**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.

· **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, ADN, IMDG, IATA**

Void

**14.2 UN proper shipping name**

· **ADR, ADN, IMDG, IATA**

Void

(Contd. on page 8)



**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

**Trade name: PalaXtreme Powder**

(Contd. of page 7)

|   |                 |
|---|-----------------|
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | Void            |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | Void            |
| · <b>14.5 Environmental hazards:</b><br>· <b>Marine pollutant:</b>                          | No              |
| · <b>14.6 Special precautions for user</b>  | Not applicable. |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b>                       | Not applicable. |
| · <b>Transport/Additional information:</b>  | -               |
| · <b>UN "Model Regulation":</b>   | 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.

· **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)
- 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)

(Contd. on page 9)





**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

**Trade name: PalaXtreme Powder**

(Contd. of page 8)

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.**

GB