



**Safety Data Sheet  
acc. to OSHA HCS**

Printing date 07/14/2022

Reviewed on 07/14/2022

## 1 Identification

· **Product identifier**

· **Trade name: PalaXtreme 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](mailto: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(s) identification

· **Classification of the substance or mixture**

Sensitization - Skin 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.

Wear protective gloves / eye protection.

If on skin: Wash with plenty of soap and water.

If skin irritation or rash occurs: Get medical advice/attention.

· **Classification system**

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



Health = 0

Fire = 1

Reactivity = 0

· **HMIS-Ratings (Scale 0-4)**



Health = 0

Fire = 1

Reactivity = 0

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- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** -

- **Dangerous components:**

72846-00-5	1-benzyl-5-phenylbarbituric acid Acute Toxicity - Oral 4, H302; Eye Irritation 2A, H319	0-5%
80-62-6	methyl methacrylate Flammable Liquids 2, H225 Skin Irritation 2, H315; Sensitization - Skin 1, H317; Specific Target Organ Toxicity - Single Exposure 3, H335	≥0.1-<1%
7659-86-1	2-ethylhexyl thioglycolate Acute Toxicity - Oral 4, H302; Sensitization - Skin 1B, H317	≥0.1-<1%
94-36-0	dibenzoyl peroxide Self-reactive substances and mixtures - Type B, H241; Organic Peroxides - Type B, H241 Eye Irritation 2A, H319; Sensitization - Skin 1, H317	≥0.1-<1%

### 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**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire fighting measures that suit the environment.
- **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** Not required.
- **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**
  - See Section 7 for information on safe handling
  - See Section 8 for information on personal protection equipment.
  - See Section 13 for disposal information.
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### 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:** None.
  - **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:**  
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.  
At this time, the other constituents have no known exposure limits.

#### 80-62-6 methyl methacrylate

PEL	Long-term value: 410 mg/m <sup>3</sup> , 100 ppm
REL	Long-term value: 410 mg/m <sup>3</sup> , 100 ppm
TLV	Short-term value: 100 ppm Long-term value: 50 ppm DSEN, A4

#### 94-36-0 dibenzoyl peroxide

PEL	Long-term value: 5 mg/m <sup>3</sup>
REL	Long-term value: 5 mg/m <sup>3</sup>
TLV	Long-term value: 5 mg/m <sup>3</sup> A4

- **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.

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- **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.
- **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:** White
- **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 does not present an explosion hazard.  
Not determined.

· **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.

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- **Solubility in / Miscibility with**
  - **Water:** Insoluble
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
  - **dynamic:** Not applicable.
  - **kinematic:** Not applicable.
- **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:** -

### 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 (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)

· **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.

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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

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

**12 Ecological information**

· **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)

**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**

**80-62-6 methyl methacrylate**

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

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

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

**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:** Avoid transfer into the environment.

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- **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

· <b>UN-Number</b> · DOT, ADR, ADN, IMDG, IATA	Void
· <b>UN proper shipping name</b> · DOT, ADR, ADN, IMDG, IATA	Void
· <b>Transport hazard class(es)</b> · DOT, ADR, ADN, IMDG, IATA · Class	Void
· <b>Packing group</b> · DOT, ADR, IMDG, IATA	Void
· <b>Environmental hazards:</b> · Marine pollutant:	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	-
· <b>UN "Model Regulation":</b>	Void

### 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.

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· **Carcinogenicity categories**

· **TLV (Threshold Limit Value)**

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 vapor.
- 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.

· **Date of preparation / last revision** 07/14/2022 / 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)
- 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
- 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)
- HMS: 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
- OSHA: Occupational Safety & Health
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit
- Flammable Liquids 2: Flammable liquids – Category 2
- Self-reactive substances and mixtures - Type B: Self-reactive substances and mixtures – Type B
- Organic Peroxides - Type B: Organic peroxides – Type B
- Acute Toxicity - Oral 4: Acute toxicity – Category 4
- Skin Irritation 2: Skin corrosion/irritation – Category 2
- Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
- Sensitization - Skin 1: Skin sensitisation – Category 1
- Sensitization - Skin 1B: Skin sensitisation – Category 1B
- Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3

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