



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

**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](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**

The product is not classified according to the CLP regulation.

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC void**

· **Classification system:**

The classification is in line with current EC lists. It is expanded, however, by information from technical literature and by information furnished by supplier companies.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008 Void**

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Additional information:**

Safety data sheet available on request.

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

· **3.2 Chemical characterisation: Mixtures**

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

· **Dangerous components:**

|                   |  |      |
|-------------------|--|------|
| CAS: 72846-00-5   | 1-Benzyl-5-phenylbarbitursäure                           | 0-5% |
| EINECS: 276-940-2 | Xi R36/37/38   |      |
|                   | Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 |      |

· **Additional information** For the wording of the listed hazard phrases refer to section 16.

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**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.
- **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:** No special measures required.
- **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).
- **7.3 Specific end use(s)** No further relevant information available.

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**SECTION 8: Exposure controls/personal protection**

- **Additional information about design of technical systems:** No further data; see item 7.
- **8.1 Control parameters**
  - **Components with critical values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
    - **Additional information:** The lists that were valid during the compilation were used as basis.
- **8.2 Exposure controls**
  - **Personal protective equipment**
    - **General protective and hygienic measures**  
The usual precautionary measures should be adhered to in handling the chemicals.
    - **Breathing equipment:** Not required.
    - **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
      - **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 trough 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:** not absolutely necessary
  - **Body protection:** Light weight protective clothing

**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Powder
      - **Colour:** According to product specification
    - **Smell:** Odourless
    - **Odour threshold:** Not determined.
  - **pH-value:** Not applicable.
  - **Change in condition**
    - **Melting point/Melting range:** Not determined

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|   |  |
|---|--|
| · <b>Boiling point/Boiling range:</b>             | Not determined   |
| · <b>Flash point:</b>                             | Not applicable   |
| · <b>Inflammability (solid, gaseous)</b>          | Not determined.  |
| · <b>Ignition temperature:</b>                    |  |
| · <b>Decomposition temperature:</b>               | Not determined.  |
| · <b>Self-inflammability:</b>                     | Product is not selfigniting.   |
| · <b>Danger of explosion:</b>                     | Product is not explosive. However, formation of explosive powder/air mixtures is possible. |
| · <b>Critical values for explosion:</b>           |  |
| · <b>Lower:</b>                                   | Not determined.  |
| · <b>Upper:</b>                                   | Not determined.  |
| · <b>Steam pressure:</b>                          | Not applicable.  |
| · <b>Density</b>                                  | Not determined   |
| · <b>Relative density</b>                         | Not determined.  |
| · <b>Vapour density</b>                           | Not applicable.  |
| · <b>Evaporation rate</b>                         | Not applicable.  |
| · <b>Solubility in / Miscibility with</b>         |  |
| · <b>Water:</b>                                   | Insoluble  |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.  |
| · <b>Viscosity:</b>                               |  |
| · <b>dynamic:</b>                                 | Not applicable.  |
| · <b>kinematic:</b>                               | Not applicable.  |
| · <b>Solvent content:</b>                         |  |
| · <b>Solids content:</b>                          | 100.0 %  |
| · <b>9.2 Other information</b>                    | No further relevant information available.   |

### 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

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
  - **Acute toxicity** Based on available data, the classification criteria are not met.

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- **Primary irritant effect:**
  - **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
  - **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.

### SECTION 12: Ecological information

- **12.1 Toxicity**
  - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 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 bodies or sewage system.
- **12.5 Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
  - **Recommendation**  
Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.
- **European waste catalogue**

|          |  |
|----------|--|
| 18 01 06 | chemicals consisting of or containing dangerous substances |
|----------|--|
- **Uncleaned packagings:**
  - **Recommendation:** Packaging can be reused or recycled after cleaning.

### SECTION 14: Transport information

- **14.1 UN-Number**
  - **ADR, ADN, IMDG, IATA** Void

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|  |  |
|--|--|
| · <b>14.2 UN proper shipping name</b><br>· <b>ADR, ADN, IMDG, IATA</b>               | Void   |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR</b><br>· <b>Class</b>           | Void<br>Flammable solids, self-reactive substances<br>and solid desensitised explosives. |
| · <b>ADN/R 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 Transport in bulk according to Annex II of<br/>Marpol and the IBC Code</b> | Not applicable.  |
| · <b>Transport/Additional information:</b>   | -  |
| · <b>UN "Model Regulation":</b>  | Void   |

**SECTION 15: Regulatory information**

· **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**

H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.

R36/37/38 Irritating to eyes, respiratory system and skin.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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