



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

Printing date 17.06.2021

Version number 4

Revision: 17.06.2021

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

- **1.1 Product identifier**
  - Trade name: **Palapress vario 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**

Skin Sens. 1 H317 May cause an allergic skin reaction.  
Aquatic Chronic 2 H411 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 CLP regulation.

    - **Hazard pictograms**  
   
GHS07 GHS09
    - **Signal word** Warning
    - **Hazard-determining components of labelling:**  
dibenzoyl peroxide  
methyl methacrylate
    - **Hazard statements**  
H317 May cause an allergic skin reaction.  
H411 Toxic to aquatic life with long lasting effects.
    - **Precautionary statements**  
P273 Avoid release to the environment.  
P280 Wear protective gloves / eye protection.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- **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

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**Dangerous components:**

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	≥1-<2.5%
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	≥1-≤5%
CAS: 72846-00-5 EINECS: 276-940-2	1-Benzyl-5-phenylbarbitursäure Acute Tox. 4, H302; Eye Irrit. 2, H319	≥0-≤5%

**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**
  - **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.

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- **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.

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

- **8.1 Control parameters**
  - **Additional information about design of technical systems:** No further data; see item 7.
  - **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.  
Not required.

· <b>DNELs</b>		
<b>94-36-0 dibenzoyl peroxide</b>		
Oral	ge.pop., l.te, syst.	1.65 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	6.6 mg/Kg/d (nd)
	ge.pop., l.te, syst.	3.3 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	11.75 mg/m3 (nd)
	ge.pop., l.te, syst.	2.9 mg/m3 (nd)
<b>80-62-6 methyl methacrylate</b>		
Dermal	worker industr., l.te., syst.	74.3 mg/Kg/d (human)
Inhalative	worker industr., l.te., syst.	210 mg/m3 (human)
· <b>PNECs</b>		
<b>80-62-6 methyl methacrylate</b>		
freshwater	0.94 mg/l (aqua)	

· **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**  
Wash hands during breaks and at the end of the work.
    - **Breathing equipment:** Not necessary if room is well-ventilated.
    - **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.

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- **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

**SECTION 9: Physical and chemical properties**

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

- **Form:** Powder
- **Colour:** Colourless  
Pink
- **Smell:** Nearly odourless
- **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

- **Melting point/freezing point:** Not determined
- **Initial boiling point and boiling range:** Not determined

· **Flash point:** Not applicable

· **Inflammability (solid, gaseous)** Not determined.

· **Ignition temperature:** 400.0 °C

· **Decomposition temperature:** Not determined.

· **Self-inflammability:** Product is not selfigniting.

· **Explosive properties:** Product is not explosive. However, formation of explosive powder/air mixtures is possible.

· **Critical values for explosion:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Steam pressure:** Not applicable.

· **Density at 20 °C**

- **Relative density** 0 g/cm<sup>3</sup>
- **Vapour density** Not determined.
- **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with**

· **Water:** Insoluble

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

- **dynamic:** Not applicable.
- **kinematic:** Not applicable.

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· **Solvent content:**

· **Solids content:** 100.0 %

· **9.2 Other information** 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
- **Additional information:** -

**SECTION 11: Toxicological information**

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

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

**94-36-0 dibenzoyl peroxide**

Oral	LD0	>2,000 mg/kg (mouse) (OECD 401)
Inhalative	LC0/4h	24.3 ppm (rat) (OECD 403)

**80-62-6 methyl methacrylate**

Oral	LD50	~7,900 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rab) (OECD 402)
Inhalative	LC50/4 h	29.8 mg/l (rat)

**72846-00-5 1-Benzyl-5-phenylbarbitursäure**

Oral	LD50	500 mg/kg (rat) (OECD 423)
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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**  
May cause an allergic skin reaction.
- **Additional toxicological information:**
  - **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.

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**SECTION 12: Ecological information**

· **12.1 Toxicity**

· **Aquatic toxicity:**

**94-36-0 dibenzoyl peroxide**

EC50/72h >2 mg/l (algae)

EC50/48h >2 mg/l (daphnia)

LC50/96h >2 mg/l (fish)

**80-62-6 methyl methacrylate**

EC50/48h 69 mg/l (daphnia)

LC50/96h 191 mg/l (fish)

· **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 product to reach ground water, water bodies or sewage system.

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

Danger to drinking water if even small quantities leak into soil.

· **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**

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:**

Packaging can be reused or recycled after cleaning.

Non contaminated packagings can be used for recycling.

**SECTION 14: Transport information**

· **14.1 UN-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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<ul style="list-style-type: none"><li>· <b>IMDG</b></li><li>· <b>IATA</b></li></ul>	<p><b>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide), MARINE POLLUTANT</b> <b>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)</b></p>
<ul style="list-style-type: none"><li>· <b>14.3 Transport hazard class(es)</b></li><li>· <b>ADR</b></li></ul> 	<ul style="list-style-type: none"><li>· <b>Class</b> 9 (M7) Miscellaneous dangerous substances and articles.</li><li>· <b>Label</b> 9</li></ul>
<ul style="list-style-type: none"><li>· <b>IMDG, IATA</b></li></ul> 	<ul style="list-style-type: none"><li>· <b>Class</b> 9 Miscellaneous dangerous substances and articles.</li><li>· <b>Label</b> 9</li></ul>
<ul style="list-style-type: none"><li>· <b>14.4 Packing group</b></li><li>· <b>ADR, IMDG, IATA</b></li></ul>	III
<ul style="list-style-type: none"><li>· <b>14.5 Environmental hazards:</b></li><li>· <b>Marine pollutant:</b></li><li>· <b>Special marking (ADR):</b></li><li>· <b>Special marking (IATA):</b></li></ul>	<p>No Symbol (fish and tree) Symbol (fish and tree) Symbol (fish and tree)</p>
<ul style="list-style-type: none"><li>· <b>14.6 Special precautions for user</b></li><li>· <b>Kemler Number:</b></li><li>· <b>EMS Number:</b></li><li>· <b>Stowage Category</b></li><li>· <b>Stowage Code</b></li></ul>	<p>Warning: Miscellaneous dangerous substances and articles. 90 F-A,S-F A SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.</p>
<ul style="list-style-type: none"><li>· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b></li></ul>	Not applicable.
<ul style="list-style-type: none"><li>· <b>Transport/Additional information:</b></li></ul>	-
<ul style="list-style-type: none"><li>· <b>ADR</b></li><li>· <b>Limited quantities (LQ)</b></li><li>· <b>Excepted quantities (EQ)</b></li><li>· <b>Transport category</b></li></ul>	<p>5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g 3</p>

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· <b>Tunnel restriction code</b>	-
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	5 kg
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· <b>UN "Model Regulation":</b>	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:**
  - 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

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*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.**

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