



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

Printing date 06/03/2017

Reviewed on 06/03/2017

## 1 Identification

· **Product identifier**

· **Trade name:** Palavit M Powder

· **Application of the substance / the mixture** Auxiliary for 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)

GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

## 2 Hazard(s) identification

· **Classification of the substance or mixture**

Skin Sens. 1 H317 May cause an allergic skin reaction.

Repr. 2 H361 Suspected of damaging fertility or the unborn child.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

· **Hazard-determining components of labeling:**

dicyclohexyl phthalate

dibenzoyl peroxide

· **Hazard statements**

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

Keep away from reducing agents, heavy metal compounds, acids and alkalis.

Wear protective gloves/protective clothing/eye protection/face protection.

Do not get in eyes, on skin, or on clothing.

Store in a dry place.

Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **Classification system**
- **NFPA ratings for USA (scale 0-4)**



- **HMIS-Ratings (Scale 0-4)**



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

**3 Composition/information on ingredients**

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

· <b>Dangerous components:</b>		
471-34-1	calcium carbonate	25-50%
94-36-0	dibenzoyl peroxide Self-react. B, H241; Org. Perox. B, H241; Eye Irrit. 2A, H319; Skin Sens. 1, H317	0-5%
84-61-7	dicyclohexyl phthalate Repr. 2, H361; Skin Sens. 1, H317	0-5%

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

**4 First-aid measures**

- **Description of first aid measures**
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** If skin irritation continues, consult a doctor.
- **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.

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**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.
- **Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.
- **Advice for firefighters**
  - **Protective equipment:** No special measures required.
- **Additional information -**

**6 Accidental release measures**

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**  
No dangerous substances are released.  
See Section 7 for information on safe handling  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

**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:**  
Store in cool, dry conditions in well sealed receptacles.
- **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:**

**471-34-1 calcium carbonate**

PEL ()	15* 5** mg/m <sup>3</sup> *total dust **respirable fraction
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REL () 10\* 5\*\* mg/m<sup>3</sup>  
\*total dust \*\*respirable fraction  
TLV () TLV withdrawn

**94-36-0 dibenzoyl peroxide**

PEL () 5 mg/m<sup>3</sup>  
REL () 5 mg/m<sup>3</sup>  
TLV () 5 mg/m<sup>3</sup>

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.

· **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

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

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 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:** Not absolutely necessary.

· **Body protection:** Light weight protective clothing

**9 Physical and chemical properties**

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

· **General Information**

· **Appearance:**

· **Form:** Powder

· **Color:** Yellow

· **Odor:** Odorless

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· <b>Odor threshold:</b>	Not determined.
· <b>pH-value:</b>	Not applicable.
· <b>Change in condition</b>	
· <b>Melting point/Melting range:</b>	undetermined
· <b>Boiling point/Boiling range:</b>	undetermined
· <b>Flash point:</b>	undetermined
· <b>Flammability (solid, gaseous)</b>	Not determined.
· <b>Ignition temperature:</b>	400 °C (752 °F)
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Vapor pressure:</b>	Not applicable.
· <b>Density:</b>	Not determined
· <b>Relative density</b>	Not determined.
· <b>Vapor 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>Other information</b>	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:** -

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**11 Toxicological information**

· **Information on toxicological effects**

· **Acute toxicity:**

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

**9011-14-7 Poly Methyl Methacrylate (PMMA)**

Oral	LD50	>5000 mg/kg (rat)
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**471-34-1 calcium carbonate**

Oral	LD50	> 2000 mg/kg (rat)
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**94-36-0 dibenzoyl peroxide**

Oral	LD50	5000 mg/kg (rat)
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Inhalative	LC50/4 h	24300 mg/l (rat)
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**84-61-7 dicyclohexyl phthalate**

Oral	LD50	30000 mg/kg (rat)
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· **Primary irritant effect:**

· **on the skin:** No irritant effect.

· **on the eye:** No irritating effect.

· **Sensitization:** Sensitization possible through skin contact.

· **Additional toxicological information:** -

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

94-36-0	dibenzoyl peroxide	3
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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.

**12 Ecological information**

· **Toxicity**

· **Aquatic toxicity:**

**94-36-0 dibenzoyl peroxide**

EC50/72h	>2 mg/l (algae)
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EC50/48h	>2 mg/l (daphnia)
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LC50/96h	>2 mg/l (fish)
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· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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· **Other adverse effects** No further relevant information available.

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**13 Disposal considerations**

- **Waste treatment methods**
  - **Recommendation**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.  
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.
- **Uncleaned packagings:**
  - **Recommendation:** Packaging can be reused or recycled after cleaning.

**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**
    - **SARA Section 355 (extremely hazardous substances)**
- None of the ingredients is listed.
- **TSCA (Toxic Substances Control Act)** None of the ingredients is listed.

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· **Carcinogeny categories**

· **TLV (Threshold Limit Value established by ACGIH)**

94-36-0	dibenzoyl peroxide	A4
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· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

· **Hazard-determining components of labeling:**

dicyclohexyl phthalate

dibenzoyl peroxide

· **Hazard statements**

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

Keep away from reducing agents, heavy metal compounds, acids and alkalis.

Wear protective gloves/protective clothing/eye protection/face protection.

Do not get in eyes, on skin, or on clothing.

Store in a dry place.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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**

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H361 Suspected of damaging fertility or the unborn child.

· **Date of preparation / last revision** 06/03/2017 / 2

· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

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*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*  
*Self-react. B: Self-reactive substances and mixtures – Type B*  
*Org. Perox. B: Organic peroxides – Type B*  
*Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A*  
*Skin Sens. 1: Skin sensitisation – Category 1*  
*Repr. 2: Reproductive toxicity – Category 2*  
**\* Data compared to the previous version altered.**

USA