



**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: **Palavit M 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** Auxiliary for 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
- **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.
- **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

- **Signal word** Warning
- **Hazard-determining components of labelling:**
dibenzoyl peroxide
dicyclohexyl phthalate
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P220 Keep away from reducing agents, heavy metal compounds, acids and alkalis.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P262 Do not get in eyes, on skin, or on clothing.
P402 Store in a dry place.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards -**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.



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SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** -

· **Dangerous components:**

CAS: 94-36-0 EINECS: 202-327-6 Reg.nr.: 01-2119511472-50	dibenzoyl peroxide Self-react. B, H241; Org. Perox. B, H241; Aquatic Acute 1, H400; Eye Irrit. 2, H319; Skin Sens. 1, H317	0-5%
CAS: 84-61-7 EINECS: 201-545-9 Reg.nr.: 01-2119978223-34-XXXX	dicyclohexyl phthalate Repr. 2, H361; Skin Sens. 1, H317; Aquatic Chronic 3, H412	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** 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.

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**

CO₂, 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**

Formation of toxic gases is possible during heating or in case of fire.

· **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 7 for information on safe handling

See Section 8 for information on personal protection equipment.

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See Section 13 for information on disposal.

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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 in cool, dry conditions in well sealed containers.
- **7.3 Specific end use(s)** No further relevant information available.

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:**

94-36-0 dibenzoyl peroxide

WEL Long-term value: 5 mg/m³

84-61-7 dicyclohexyl phthalate

WEL Long-term value: 5 mg/m³

· **DNELs**

94-36-0 dibenzoyl peroxide

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/m ³ (nd)
	ge.pop., l.te, syst.	2.9 mg/m ³ (nd)

84-61-7 dicyclohexyl phthalate

Dermal	worker industr., l.te., syst.	6.6 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	11.75 mg/m ³ (nd)

· **PNECs**

84-61-7 dicyclohexyl phthalate

freshwater	0.000602 mg/l (nd)
marine water	0.000602 mg/l (nd)
STP	0.35 mg/l (nd)
sedim., dw, fre.wat.	0.388 mg/Kg (nd)

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

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· 8.2 Exposure controls

· Personal protective equipment

· General protective and hygienic measures

Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the 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

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

· Form: Powder

· Colour: Yellow

· Smell: Odourless

· Odour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

· Melting point/Melting range: Not determined

· Boiling point/Boiling range: Not determined

· Flash point: Not determined

· Inflammability (solid, gaseous) Not determined.

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· Ignition temperature:	400 °C
· Decomposition temperature:	Not determined.
· Self-inflammability:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive.
· Critical values for explosion:	
· Lower:	Not determined.
· Upper:	Not determined.
· Steam pressure:	Not applicable.
· Density	Not determined
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with	
· Water:	Insoluble
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· dynamic:	Not applicable.
· kinematic:	Not applicable.
· 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:		
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:**
 - **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.

SECTION 12: Ecological information

· **12.1 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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- **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.
- **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.

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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.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN-Number
· ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · 14.4 Packing group
· ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards:
· Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | 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**
 - 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.
 - H400 Very toxic to aquatic life.
 - H412 Harmful to aquatic life with long lasting effects.

- **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)

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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
Self-react. B: Self-reactive substances and mixtures – Type B
Org. Perox. B: Organic peroxides – Type B
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Repr. 2: Reproductive toxicity – Category 2
Aquatic Acute 1: Hazardous to the aquatic environment - acute 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.**

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