



**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: **Palavit 55 VS 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 Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very 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.

H410 Very 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	≥2.5-≤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: 1953-33-9	5-butyl-1H,3H,5H-pyrimidine-2,4,6-trione Skin Irrit. 2, H315; 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**

· **General information** No special measures required.

· **After skin contact**

Instantly wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· **After eye contact**

Rinse opened eye for several minutes under running water. Then consult doctor.

· **After swallowing**

In case of persistent symptoms consult doctor.

Rinse out mouth and then drink plenty of water.

· **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.

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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 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/m <sup>3</sup> (nd)
	ge.pop., l.te., syst.	2.9 mg/m <sup>3</sup> (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/m <sup>3</sup> (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:**  
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.

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- **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:** 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** 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.

· **9.2 Other information** No further relevant information available.



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**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.

· **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)

- **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)
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.

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- **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**  
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.

**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)
  - **IMDG, IATA** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)
- **14.3 Transport hazard class(es)**
  - **ADR**  

  - **Class** 9 (M7) Miscellaneous dangerous substances and articles.
  - **Label** 9

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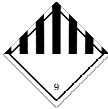
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· **IMDG**



· **Class**

9 Miscellaneous dangerous substances and articles.

· **Label**

9

· **IATA**



· **Class**

9 Miscellaneous dangerous substances and articles.

· **Label**

9

· **14.4 Packing group**  
· **ADR, IMDG, IATA**

III

· **14.5 Environmental hazards:**

· **Marine pollutant:**

No

· **Special marking (ADR):**

Symbol (fish and tree)

· **Special marking (IATA):**

Symbol (fish and tree)

· **14.6 Special precautions for user**

Warning: Miscellaneous dangerous substances and articles.

· **Kemler Number:**

90

· **EMS Number:**

F-A,S-F

· **Stowage Category**

A

· **Stowage Code**

SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.

· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

· **Transport/Additional information:**

-

· **ADR**

· **Limited quantities (LQ)**

5 kg

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

· **Transport category**

3

· **Tunnel restriction code**

-

· **IMDG**

· **Limited quantities (LQ)**

5 kg

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· <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 100 t**
    - **Qualifying quantity (tonnes) for the application of upper-tier requirements 200 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.
- 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
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- 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

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