



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

Printing date 01/30/2024

Reviewed on 01/30/2024

## 1 Identification

· **Product identifier**

· Trade name: **Palavit 55 VS powder**

· -

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

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

## 2 Hazard(s) identification

· **Classification of the substance or mixture**

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **GHS label elements**

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

· **Hazard pictograms**



GHS07

· **Signal word** Warning

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

dibenzoyl peroxide

methyl methacrylate

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid release to the environment.

Wear protective gloves / eye protection.

If skin irritation or rash occurs: Get medical advice/attention.

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**



Health = 1

Fire = 1

Reactivity = 0

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· **HMIS-Ratings (Scale 0-4)**

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HEALTH	0	Health = 0
FIRE	1	Fire = 1
REACTIVITY	0	Reactivity = 0

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**3 Composition/information on ingredients**

· **Chemical characterization: Mixtures**

- **Description:** Product based on methacrylate copolymerisates

· **Dangerous components:**

94-36-0	dibenzoyl peroxide Self-reactive substances and mixtures - Type B, H241; Organic Peroxides - Type B, H241 Eye Irritation 2A, H319; Sensitization - Skin 1, H317	≥1-≤5%
80-62-6	methyl methacrylate Flammable Liquids 2, H225 Skin Irritation 2, H315; Sensitization - Skin 1, H317; Specific Target Organ Toxicity - Single Exposure 3, H335	≥1-≤5%
1953-33-9	5-butyl-1H,3H,5H-pyrimidine-2,4,6-trione Skin Irritation 2, H315; Eye Irritation 2A, H319	≥0-≤5%
13463-67-7	Titanium dioxide Carcinogenicity 2, H351	≥0.1-<1%

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

**4 First-aid measures**

· **Description of first aid measures**

- **General information** No special measures required.
- **After skin contact**  
Immediately 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 a doctor.
- **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** No further relevant information available.
- **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 8 for information on personal protection equipment.
- 

### 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:** Keep cool, if possible (not above 25 °C).
- **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 section 7.
- **Control parameters**
  - **Components with limit values that require monitoring at the workplace:**  
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.  
At this time, the remaining constituent has no known exposure limits.

#### 94-36-0 dibenzoyl peroxide

PEL Long-term value: 5 mg/m<sup>3</sup>

REL Long-term value: 5 mg/m<sup>3</sup>

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TLV	Long-term value: 5 mg/m <sup>3</sup> A4
<b>80-62-6 methyl methacrylate</b>	
PEL	Long-term value: 410 mg/m <sup>3</sup> , 100 ppm
REL	Long-term value: 410 mg/m <sup>3</sup> , 100 ppm
TLV	Short-term value: 100 ppm Long-term value: 50 ppm DSEN, A4

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

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures** Wash hands before breaks and at the end of 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.

· **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

**9 Physical and chemical properties**

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

· **General Information**

· **Appearance:**

· **Form:**

Powder

· **Color:**

Colorless

Pink

· **Odor:**

Odorless

· **Odor threshold:**

Not determined.

· **pH-value:**

Mixture is non-soluble (in water).

· **Change in condition**

· **Melting point/Melting range:**

undetermined

· **Boiling point/Boiling range:**

undetermined

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· <b>Flash point:</b>	Not applicable
· <b>Flammability (solid, gaseous)</b>	Not determined.
· <b>Auto igniting:</b>	400.0 °C (752 °F)
· <b>Decomposition temperature:</b>	Not determined.
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product is not explosive. However, formation of explosive powder/air mixture mis possible.
· <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>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

**11 Toxicological information**

- **Information on toxicological effects**
- **Acute toxicity:**

· <b>LD/LC50 values that are relevant for classification:</b>		
<b>94-36-0 dibenzoyl peroxide</b>		
Oral	LD0	>2,000 mg/kg (mouse) (OECD 401)
Inhalative	LC0/4h	24.3 ppm (rat) (OECD 403)

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**80-62-6 methyl methacrylate**

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

· **Primary irritant effect:**

- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.

· **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

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

94-36-0	dibenzoyl peroxide	3
	iron oxide Goethit FeO(OH)	3

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Reproductive toxicity** Based on available data, the classification criteria are not met.

**12 Ecological information**

· **Toxicity**

· **Aquatic toxicity:**

**94-36-0 dibenzoyl peroxide**

EC50/72h	0.042 mg/l (algae) (OECD 201)
EC50/48h	0.11 mg/l (daphnia) (OECD 202)
LC50/96h	0.06 mg/l (fish) (OECD 203)
ErC50 / 72 h	0.071 mg/l (algae) (OECD 201)
NOEC / 72h	0.02 mg/l (algae) (OECD 201)
NOEC / 96h	0.032 mg/l (fish) (OECD 203)
NOEC / 48h	0.076 mg/l (daphnia) (OECD 202)
ErC10	0.001 mg/L /21d (daphnia) (OECD 211)

**80-62-6 methyl methacrylate**

EC50/21d	49 mg/L (daphnia) (OECD 211)
EC50/48h	69 mg/l (daphnia) (EPA OTS 797.1300)
NOEC / 21d	37 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>110 mg/l (algae) (OECD 201)

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NOEC / 72h	110 mg/l (algae) (OECD 201)
NOEC / 48h	48 mg/l (daphnia) (EPA OTS 797.1300)
EbC50 / 72h	>110 mg/l (algae) (OECD 201)
NOEC/ 35d	9.4 mg/L (fish) (OECD 210)
LC50/ 35d	33.7 mg/L (fish) (OECD 210)

· **Persistence and degradability**

**94-36-0 dibenzoyl peroxide**

biodegradability 71 % /28d (not defined) (OECD 301D)

**80-62-6 methyl methacrylate**

biodegradability 94 % /14d (not defined) (OECD 301C)

· **Behavior in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.
- **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 course or sewage system.

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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

**13 Disposal considerations**

· **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.

**14 Transport information**

· **UN-Number**

· DOT, ADR, IMDG, IATA UN3077

· **UN proper shipping name**

· DOT Environmentally hazardous substance, solid, n.o.s.  
· ADR 3077 ENVIRONMENTALLY HAZARDOUS  
SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)

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· <b>IMDG, IATA</b>	<b>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)</b>
· <b>Transport hazard class(es)</b>	
· <b>DOT, IMDG</b>	
	
· <b>Class</b>	9 Miscellaneous dangerous substances and articles
· <b>Label</b>	9
· <b>ADR</b>	
	
· <b>Class</b>	9 (M7) Miscellaneous dangerous substances and articles
· <b>Label</b>	9
· <b>IATA</b>	
	
· <b>Class</b>	9 Miscellaneous dangerous substances and articles
· <b>Label</b>	9
· <b>Packing group</b>	
· <b>DOT, ADR, IMDG, IATA</b>	III
· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>Special marking (ADR):</b>	Symbol (fish and tree)
· <b>Special marking (IATA):</b>	Symbol (fish and tree)
· <b>Special precautions for user</b>	Warning: Miscellaneous dangerous substances and articles
· <b>Hazard identification number (Kemler code):</b>	90
· <b>EMS Number:</b>	F-A,S-F
· <b>Stowage Category</b>	A
· <b>Stowage Code</b>	SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

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· <b>Transport/Additional information:</b> -	
· <b>ADR</b>	
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· <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

**15 Regulatory information**

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.

· **Sara**

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

94-36-0 dibenzoyl peroxide

· **Proposition 65**

· **Prop 65 - Chemicals known to cause cancer**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogeny categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

94-36-0 dibenzoyl peroxide

A4

iron oxide Goethit FeO(OH)

A4

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· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **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**

- H225 Highly flammable liquid and vapor.
- 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.
- H351 Suspected of causing cancer.

· **Date of preparation / last revision** 01/30/2024

· **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
- DOT: US Department of Transportation
- IATA: International Air Transport Association
- 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
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- NIOSH: National Institute for Occupational Safety
- OSHA: Occupational Safety & Health
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit
- Flammable Liquids 2: Flammable liquids – Category 2
- Self-reactive substances and mixtures - Type B: Self-reactive substances and mixtures – Type B
- Organic Peroxides - Type B: Organic peroxides – Type B
- Skin Irritation 2: Skin corrosion/irritation – Category 2
- Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
- Sensitization - Skin 1: Skin sensitisation – Category 1
- Carcinogenicity 2: Carcinogenicity – Category 2
- Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3

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