



**Safety Data Sheet  
according to HPR, Schedule 1**

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 identification

· **Classification of the substance or mixture**

Skin Sensitizer - Category 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

(Contd. on page 2)

CA



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**Trade name: Palavit 55 VS powder**

**· HMIS-Ratings (Scale 0-4)**

(Contd. of page 1)

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

· **Other hazards -**

**3 Composition/Information on ingredients**

· **Chemical characterization: Mixtures**

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

· **Dangerous components:**

94-36-0	dibenzoyl peroxide Organic Peroxides – Type B, H241 Eye Irritation - Category 2A, H319; Skin Sensitizer - Category 1, H317	≥1-≤5% w/w *
80-62-6	methyl methacrylate Flammable Liquids - Category 2, H225 Skin Irritation - Category 2, H315; Skin Sensitizer - Category 1, H317; Specific Target Organ Toxicity - Single Exposure - Category 3, H335	≥1-≤5% w/w *
1953-33-9	5-butyl-1H,3H,5H-pyrimidine-2,4,6-trione Skin Irritation - Category 2, H315; Eye Irritation - Category 2A, H319	≥0-≤5% w/w *

\* Actual concentration ranges are withheld as a trade secret.

· **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.

CA

(Contd. on page 3)



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(Contd. of page 2)

**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**

· <b>Components with limit values that require monitoring at the workplace:</b>	
<b>94-36-0 dibenzoyl peroxide</b>	
EL	TWA: 5 mg/m <sup>3</sup>
EV	TWA: 5 mg/m <sup>3</sup>
<b>80-62-6 methyl methacrylate</b>	
EL	STEL: 100 ppm
	TWA: 50 ppm
	S(D)

(Contd. on page 4)

CA



**Safety Data Sheet**  
**according to HPR, Schedule 1**

Printing date 01/30/2024

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**Trade name: Palavit 55 VS powder**

(Contd. of page 3)

EV STEL: 100 ppm  
TWA: 50 ppm

· **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

· **Flash point:**

Not applicable

· **Flammability (solid, gaseous)**

Not determined.

· **Auto igniting:**

400,0 °C (752 °F)

· **Decomposition temperature:**

Not determined.

(Contd. on page 5)



**Safety Data Sheet**  
according to HPR, Schedule 1

Printing date 01/30/2024

Reviewed on 01/30/2024

**Trade name: Palavit 55 VS powder**

(Contd. of page 4)

· <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:**

- **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) weight of evidence
Dermal	LD50	>5.000 mg/kg (guinea pig) (OECD 402)
Inhalative	LC50/4 h	29,8 mg/l (rat)

(Contd. on page 6)



**Safety Data Sheet**  
according to HPR, Schedule 1

Printing date 01/30/2024

Reviewed on 01/30/2024

**Trade name: Palavit 55 VS powder**

(Contd. of page 5)

- **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.

· **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)
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)

(Contd. on page 7)

CA



**Safety Data Sheet  
according to HPR, Schedule 1**

Printing date 01/30/2024

Reviewed on 01/30/2024

**Trade name: Palavit 55 VS powder**

(Contd. of page 6)

· **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/TDG, ADR, IMDG, IATA**

UN3077

· **UN proper shipping name**

· **DOT/TDG**

· **ADR**

Environmentally hazardous substance, solid, n.o.s.  
3077 Environmentally hazardous substance, solid,  
n.o.s. (dibenzoyl peroxide)

· **IMDG, IATA**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE,  
SOLID, N.O.S. (dibenzoyl peroxide)

(Contd. on page 8)



**Safety Data Sheet**  
according to HPR, Schedule 1

Printing date 01/30/2024

Reviewed on 01/30/2024

**Trade name: Palavit 55 VS powder**

(Contd. of page 7)

· **Transport hazard class(es)**

· **DOT, IMDG**



· **Class**

9 Miscellaneous dangerous substances and articles

· **Label**

9

· **ADR**



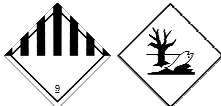
· **Class**

9 (M7) Miscellaneous dangerous substances and articles

· **Label**

9

· **IATA**



· **Class**

9 Miscellaneous dangerous substances and articles

· **Label**

9

· **Packing group**

· DOT/TDG, ADR, IMDG, IATA

III

· **Environmental hazards:**

· **Marine pollutant:**

No

· **Special marking (ADR):**

Symbol (fish and tree)

· **Special marking (IATA):**

Symbol (fish and tree)

· **Special precautions for user**

Warning: Miscellaneous dangerous substances and articles

· **Hazard identification number (Kemler code):** 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.

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

· **Transport/Additional information:**

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(Contd. on page 9)





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(Contd. of page 8)

· <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> · <b>Excepted quantities (EQ)</b>	5 kg 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.

· **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 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.

· **Date of the latest revision of the safety data sheet** 01/30/2024

· **Abbreviations and acronyms:**

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

(Contd. on page 10)

CA



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Printing date 01/30/2024

Reviewed on 01/30/2024

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vPvB: very Persistent and very Bioaccumulative

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

(Contd. of page 9)

CA