



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

Printing date 07/07/2022

Reviewed on 07/04/2022

1 Identification

· **Product identifier**

· **Trade name: Paladon 65 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

· **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:**

methyl methacrylate

dibenzoyl peroxide

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid release to the environment.

Wear protective gloves / eye protection.

If on skin: Wash with plenty of soap and water.

· **Classification system**

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



Health = 1

Fire = 1

Reactivity = 0

· **HMIS-Ratings (Scale 0-4)**



Health = 0

Fire = 1

Reactivity = 0

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· **Other hazards -**

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3 Composition/Information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Product based on methacrylate copolymerisates

· **Dangerous components:**

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 *
94-36-0	dibenzoyl peroxide Organic Peroxides – Type B, H241 Eye Irritation - Category 2A, H319; Skin Sensitizer - Category 1, H317	≥0,1-<0,5% w/w *

* Actual concentration ranges are withheld as a trade secret.

4 First-aid measures

- **Description of first aid measures**
 - **General information** No special measures required.
 - **After inhalation** Supply fresh air; consult doctor in case of complaints.
 - **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.
 - **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.

5 Fire-fighting measures

- **Extinguishing media**
 - **Suitable extinguishing agents**
CO₂, 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**
Avoid contact with eyes and skin.
- **Environmental precautions:** Prevent seepage into sewage system, workpits and cellars.
- **Methods and material for containment and cleaning up:** Pick up mechanically.

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- **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 item 7.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

80-62-6 methyl methacrylate

EL STEL: 100 ppm
TWA: 50 ppm
S(D)

EV STEL: 100 ppm
TWA: 50 ppm

94-36-0 dibenzoyl peroxide

EL TWA: 5 mg/m³

EV TWA: 5 mg/m³

· **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:**
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
Check protective gloves prior to each use for their proper condition.
 - **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.

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- **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

· **Color:** 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.

· **Ignition temperature:** 400,0 °C (752 °F)

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive. However, formation of explosive powder/air mixture mis possible.

· **Explosion limits:**

· **Lower:** Not determined.

· **Upper:** Not determined.

· **Vapor pressure:** Not applicable.

· **Density at 20 °C (68 °F):** 0 g/cm³

· **Relative density** Not determined.

· **Vapor 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.

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- | | |
|----------------------------|--|
| · Solvent content: | |
| · Solids content: | 100,0 % |
| · Other information | 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:** -

11 Toxicological information

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

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

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)

94-36-0 dibenzoyl peroxide

Oral	LD0	>2.000 mg/kg (mouse) (OECD 401)
Inhalative	LC0/4h	24,3 ppm (rat) (OECD 403)

- **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
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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

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12 Ecological information

· Toxicity

· Aquatic toxicity:

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)

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)

· Persistence and degradability

80-62-6 methyl methacrylate

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

94-36-0 dibenzoyl peroxide

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

· 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.

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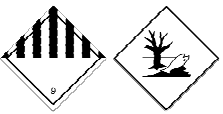
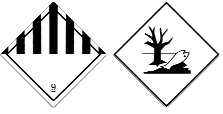
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- **Uncleaned packagings:**
- **Recommendation:**
Disposal must be made according to official regulations.
Non contaminated packagings can be used for recycling.

14 Transport information

<ul style="list-style-type: none"> · UN-Number · DOT/TDG · ADR, IMDG, IATA 	<p>Void UN3077</p>
<ul style="list-style-type: none"> · UN proper shipping name · DOT/TDG · ADR · IMDG · IATA 	<p>Void 3077 Environmentally hazardous substance, solid, n.o.s. (dibenzoyl peroxide) ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide), MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)</p>
<ul style="list-style-type: none"> · Transport hazard class(es) · DOT/TDG (Transport dangerous goods): · Class 	<p>Void</p>
<ul style="list-style-type: none"> · ADR 	<p>9 (M7) Miscellaneous dangerous substances and articles 9</p>
<ul style="list-style-type: none"> · IMDG, IATA 	<p>9 Miscellaneous dangerous substances and articles 9</p>
<ul style="list-style-type: none"> · Packing group · DOT/TDG · ADR, IMDG, IATA 	<p>Void III</p>
<ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: · Special marking (ADR): · Special marking (IATA): 	<p>No Symbol (fish and tree) Symbol (fish and tree) Symbol (fish and tree)</p>

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· Special precautions for user	<i>Warning: Miscellaneous dangerous substances and articles</i>
· 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:	-
· ADR	
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· IMDG	
· 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
· UN "Model Regulation":	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** 07/07/2022 / 3
- **Abbreviations and acronyms:**
 - IMDG: International Maritime Code for Dangerous Goods
 - DOT: US Department of Transportation

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

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