



**Safety data sheet  
according to 1907/2006/EC, Article 31**

Printing date 07.07.2022

Version number 4 (replaces version 3)

Revision: 04.07.2022

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

· **1.1 Product identifier**

· Trade name: **Paladon 65 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 prosthesis

· **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 Chronic 2 H411 (M=10) 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 GB CLP regulation.

· **Hazard pictograms**



GHS07 GHS09

· **Signal word** Warning

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

methyl methacrylate

dibenzoyl peroxide

· **Hazard statements**

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P273 Avoid release to the environment.

P280 Wear protective gloves / eye protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

· **3.2 Mixtures**

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

(Contd. on page 2)



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Version number 4 (replaces version 3)

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**Trade name: Paladon 65 powder**

(Contd. of page 1)

**Dangerous components:**

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: 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	≥0.25-<1%

**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
  - **General information** No special measures required.
  - **After inhalation** Supply fresh air; consult doctor in case of symptoms.
  - **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.
  - **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**  
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**  
Avoid contact with eyes and skin.
- **6.2 Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- **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.

(Contd. on page 3)



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**according to 1907/2006/EC, Article 31**

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Version number 4 (replaces version 3)

Revision: 04.07.2022

**Trade name: Paladon 65 powder**

(Contd. of page 2)

- **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**

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

**80-62-6 methyl methacrylate**

WEL (Great Britain)	Short-term value: 416 mg/m <sup>3</sup> , 100 ppm Long-term value: 208 mg/m <sup>3</sup> , 50 ppm
IOELV (European Union)	Short-term value: 100 ppm Long-term value: 50 ppm

**94-36-0 dibenzoyl peroxide**

WEL (Great Britain)	Long-term value: 5 mg/m <sup>3</sup>
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· **DNELs**

**80-62-6 methyl methacrylate**

Oral	general population, long term, systemic	8.2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.67 mg/Kg/d (not defined)
	general population, long term, systemic	8.2 mg/Kg/d (not defined)
Inhalative	worker industrial, acute, local	416 mg/m <sup>3</sup> (not defined)
	worker industrial, long term, systemic	348.4 mg/m <sup>3</sup> (not defined)
	worker industrial, long term, local	208 mg/m <sup>3</sup> (not defined)
	general population, acute, local	208 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	74.3 mg/m <sup>3</sup> (not defined)

**94-36-0 dibenzoyl peroxide**

Oral	general population, long term, systemic	2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.3 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	39 mg/m <sup>3</sup> (not defined)

· **PNECs**

**80-62-6 methyl methacrylate**

freshwater	0.94 mg/l (not defined)
marine water	0.094 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	10.2 mg/Kg (not defined)
sediment, dry weight, marine water	0.102 mg/Kg (not defined)
soil, dry weight	1.48 mg/Kg (not defined)

**94-36-0 dibenzoyl peroxide**

freshwater	0.00002 mg/l (not defined)
marine water	0.000002 mg/l (not defined)
sewage treatment plant	0.35 mg/l (not defined)

(Contd. on page 4)



**Safety data sheet**  
**according to 1907/2006/EC, Article 31**

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Version number 4 (replaces version 3)

Revision: 04.07.2022

**Trade name: Paladon 65 powder**

(Contd. of page 3)

sediment, dry weight, freshwater	0.013 mg/Kg (not defined)
sediment, dry weight, marine water	0.001 mg/Kg (not defined)
soil, dry weight	0.003 mg/Kg (not defined)

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

· **8.2 Exposure controls**

· **Appropriate engineering controls** No further data; see item 7.

· **Individual protection measures, such as 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.

· **Hand protection**

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.

· **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/face 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**

· **Physical state**

Solid.

· **Colour:**

Colourless

Pink

· **Smell:**

Odourless

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Not determined

· **Boiling point or initial boiling point and boiling range**

Not determined

· **Flammability**

Not determined.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

Not applicable

· **Ignition temperature:**

400.0 °C

· **Decomposition temperature:**

Not determined.

· **SADT**

· **pH**

Mixture is non-soluble (in water).

(Contd. on page 5)



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**according to 1907/2006/EC, Article 31**

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Version number 4 (replaces version 3)

Revision: 04.07.2022

**Trade name: Paladon 65 powder**

(Contd. of page 4)

· <b>Viscosity:</b>	
· Kinematic viscosity	Not applicable.
· dynamic:	Not applicable.
· <b>Solubility</b>	
· Water:	Insoluble
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Steam pressure:</b>	Not applicable.
· <b>Density and/or relative density</b>	
· Density at 20 °C	0 g/cm <sup>3</sup>
· Relative density	Not determined.
· Vapour density	Not applicable.

· <b>9.2 Other information</b>	No further relevant information available.
· <b>Appearance:</b>	
· Form:	Powder
· <b>Important information on protection of health and environment, and on safety.</b>	
· Self-inflammability:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive powder/air mixtures is possible.
· Solvent content:	
· Solids content:	100.0 %
· <b>Change in condition</b>	
· Evaporation rate	Not applicable.

· <b>Information with regard to physical hazard classes</b>	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

**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.

(Contd. on page 6)



**Safety data sheet  
according to 1907/2006/EC, Article 31**

Printing date 07.07.2022

Version number 4 (replaces version 3)

Revision: 04.07.2022

**Trade name: Paladon 65 powder**

(Contd. of page 5)

- **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 hazard classes as defined in Regulation (EC) No 1272/2008**
  - **Acute toxicity** Based on available data, the classification criteria are not met.

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

**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)

**94-36-0 dibenzoyl peroxide**

Oral	LD0	>2,000 mg/kg (mouse) (OECD 401)
Inhalative	LC0/4h	24.3 ppm (rat) (OECD 403)

- **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.
- **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.

- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information**

- **12.1 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)

(Contd. on page 7)



**Safety data sheet**  
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Version number 4 (replaces version 3)

Revision: 04.07.2022

**Trade name: Paladon 65 powder**

(Contd. of page 6)

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)

· **12.2 Persistence and degradability**

**80-62-6 methyl methacrylate**

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

**94-36-0 dibenzoyl peroxide**

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

· **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 Endocrine disrupting properties**

For information on endocrine disrupting properties see section 11.

· **12.7 Other adverse effects**

· **Additional ecological information:**

· **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

**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 or ID number**

· **ADR, IMDG, IATA**

UN3077

· **14.2 UN proper shipping name**

· **ADR**

3077 ENVIRONMENTALLY HAZARDOUS  
SUBSTANCE, SOLID, N.O.S. (dibenzoyl  
peroxide)

(Contd. on page 8)

GB



**Safety data sheet**  
**according to 1907/2006/EC, Article 31**

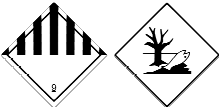

Printing date 07.07.2022

Version number 4 (replaces version 3)

Revision: 04.07.2022

**Trade name: Paladon 65 powder**

(Contd. of page 7)

<ul style="list-style-type: none"> <li>· <b>IMDG</b></li> <li>· <b>IATA</b></li> </ul>	<p><b>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide), MARINE POLLUTANT</b> <b>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)</b></p>
<ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR</b></li> </ul>	
	
<ul style="list-style-type: none"> <li>· <b>Class</b></li> <li>· <b>Label</b></li> </ul>	<p>9 (M7) Miscellaneous dangerous substances and articles. 9</p>
<ul style="list-style-type: none"> <li>· <b>IMDG, IATA</b></li> </ul>	
	
<ul style="list-style-type: none"> <li>· <b>Class</b></li> <li>· <b>Label</b></li> </ul>	<p>9 Miscellaneous dangerous substances and articles. 9</p>
<ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>	<p>III</p>
<ul style="list-style-type: none"> <li>· <b>14.5 Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> <li>· <b>Special marking (ADR):</b></li> <li>· <b>Special marking (IATA):</b></li> </ul>	<p>No Symbol (fish and tree) Symbol (fish and tree) Symbol (fish and tree)</p>
<ul style="list-style-type: none"> <li>· <b>14.6 Special precautions for user</b></li> <li>· <b>Kemler Number:</b></li> <li>· <b>EMS Number:</b></li> <li>· <b>Stowage Category</b></li> <li>· <b>Stowage Code</b></li> </ul>	<p>Warning: Miscellaneous dangerous substances and articles. 90 F-A,S-F A SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.</p>
<ul style="list-style-type: none"> <li>· <b>14.7 Maritime transport in bulk according to IMO instruments</b></li> </ul>	<p>Not applicable.</p>
<ul style="list-style-type: none"> <li>· <b>Transport/Additional information:</b></li> </ul>	<p>-</p>
<ul style="list-style-type: none"> <li>· <b>ADR</b></li> <li>· <b>Limited quantities (LQ)</b></li> <li>· <b>Excepted quantities (EQ)</b></li> <li>· <b>Transport category</b></li> </ul>	<p>5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g 3</p>

(Contd. on page 9)





**Safety data sheet**  
**according to 1907/2006/EC, Article 31**

Printing date 07.07.2022

Version number 4 (replaces version 3)

Revision: 04.07.2022

**Trade name: Paladon 65 powder**

(Contd. of page 8)

· <b>Tunnel restriction code</b>	(-)
· <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

### 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** 200 t
    - **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 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:**

- SADT: Self Accelerating Decomposition Temperature
- 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 (UK REACH)
- PNEC: Predicted No-Effect Concentration (UK 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

(Contd. on page 10)



**Safety data sheet**  
**according to 1907/2006/EC, Article 31**

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Version number 4 (replaces version 3)

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**Trade name: Paladon 65 powder**

(Contd. of page 9)

*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*  
*Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2*  
· \* **Data compared to the previous version altered.**

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