



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

Printing date 03.06.2017

Version number 4

Revision: 03.06.2017

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

· **1.1 Product identifier**

· Trade name: **Paladent RR 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

· **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.

· **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

· **Signal word** Warning

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

dibenzoyl peroxide

· **Hazard statements**

H317 May cause an allergic skin reaction.

· **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P321 Specific treatment (see on this label).

P363 Wash contaminated clothing before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** -

· **Dangerous components:**

| | | |
|---------------------------|--|------|
| CAS: 94-36-0 | dibenzoyl peroxide | 0-5% |
| EINECS: 202-327-6 | Self-react. B, H241; Org. Perox. B, H241; Aquatic Acute 1, H400; | |
| Reg.nr.: 01-2119511472-50 | Eye Irrit. 2, H319; Skin Sens. 1, H317 | |

· **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**

· **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. Then consult doctor.

· **After swallowing**

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult doctor.

Seek immediate medical advice.

· **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**

CO₂, 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**

Formation of toxic gases is possible during heating or in case of fire.

· **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**

Wear protective equipment. Keep unprotected persons away.

· **6.2 Environmental precautions:** No special measures required.

· **6.3 Methods and material for containment and cleaning up:**

Collect mechanically.

Send for recovery or disposal in suitable containers.

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· **6.4 Reference to other sections** See Section 8 for information on personal protection equipment.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Wear protective equipment. Keep unprotected persons away.
 - **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:** None.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

· **8.1 Control parameters**

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

94-36-0 dibenzoyl peroxide

WEL | Long-term value: 5 mg/m³

· **DNELs**

94-36-0 dibenzoyl peroxide

| | | |
|------------|-------------------------------|------------------------------|
| 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 ³ (nd) |
| | ge.pop., l.te, syst. | 2.9 mg/m ³ (nd) |

- **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**

Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.

· **Breathing equipment:** Filter P3.

· **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

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

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

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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 trough 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

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

· **Form:** Powder

· **Colour:** Pink

· **Smell:** Odourless

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· **Melting point/Melting range:** Not determined

· **Boiling point/Boiling range:** Not determined

· **Flash point:** Not applicable

· **Inflammability (solid, gaseous)** Not determined.

· **Ignition temperature:**

· **Decomposition temperature:** Not determined.

· **Self-inflammability:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive.

· **Critical values for explosion:**

· **Lower:** Not determined.

· **Upper:** Not determined.

· **Steam pressure:** Not applicable.

· **Density**

· **Relative density** Not determined

· **Vapour density** Not applicable.

· **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with**

· **Water:** Insoluble

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| | |
|---|--|
| · Partition coefficient (n-octanol/water): | Not determined. |
| · Viscosity: | |
| · dynamic: | Not applicable. |
| · kinematic: | Not applicable. |
| · Solvent content: | |
| · Solids content: | 100.0 % |
| · 9.2 Other information | No further relevant information available. |

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
- **Additional information:** -

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: | | |
| 9011-14-7 Polymethylmethacrylat | | |
| Oral | LD50 | >5000 mg/kg (rat) |
| 94-36-0 dibenzoyl peroxide | | |
| Oral | LD50 | 5000 mg/kg (rat) |
| Inhalative | LC50/4 h | 24300 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.
- **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.

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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)

· **12.2 Persistence and degradability** No further relevant information available.

· **12.3 Bioaccumulative potential** No further relevant information available.

· **12.4 Mobility in soil** No further relevant information available.

· **Additional ecological information:**

· **General notes:** Avoid transfer into the environment.

· **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**

Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, ADN, IMDG, IATA**

Void

· **14.2 UN proper shipping name**

· **ADR, ADN, IMDG, IATA**

Void

· **14.3 Transport hazard class(es)**

· **ADR, ADN, IMDG, IATA**

· **Class**

Void

· **14.4 Packing group**

· **ADR, IMDG, IATA**

Void

· **14.5 Environmental hazards:**

· **Marine pollutant:**

No

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- | | |
|--|-----------------|
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

- **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**

- H241 Heating may cause a fire or explosion.

- H317 May cause an allergic skin reaction.

- H319 Causes serious eye irritation.

- H400 Very toxic to aquatic life.

- **Abbreviations and acronyms:**

- RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

- IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

- ICAO: International Civil Aviation Organisation

- ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

- ADR: Accord européen sur le transport 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)

- LC50: Lethal concentration, 50 percent

- LD50: Lethal dose, 50 percent

- PBT: Persistent, Bioaccumulative and Toxic

- vPvB: very Persistent and very Bioaccumulative

- Self-react. B: Self-reactive substances and mixtures – Type B

- Org. Perox. B: Organic peroxides – Type B

- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

- Skin Sens. 1: Skin sensitisation – Category 1

- Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

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