

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

- **1.1 Product identifier**
- **Trade name: Palacos R-, Palacos LV-, Palacos MV-, Palamed-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** Bone cement
- **Manufacturer/Supplier:**
Heraeus Medical GmbH
Philipp-Reis-Str. 8-13, D-61273 Wehrheim
Germany
Tel.: +49 (0)6181-353000
- **Further information obtainable from:** sds@heraeus.com
- **1.4 Emergency telephone number:**
Emergency Contact (24-Hour-Phone Number)
GBK-GmbH, Ingelheim: (international) +49 (0)6132-84463
GBK/ Infotrac ID 105241: (China domestic) 4001 200 761











SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008 -**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**
Contains dibenzoyl peroxide. May produce an allergic reaction.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**

- **Dangerous components:**

| | | |
|---------------------------|---|--------|
| CAS: 94-36-0 | dibenzoyl peroxide | < 1.0% |
| EINECS: 202-327-6 |  Xi R36;  Xi R43;  E R3;  O R7;  N R50/53 | |
| Reg.nr.: 01-2119511472-50 |  Self-react. B, H241;  Org. Perox. B, H241;  Aquatic Acute 1, H400;  Eye Irrit. 2, H319;  Skin Sens. 1, H317 | |

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

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· **Non dangerous components:**

| | | |
|-------------------|-------------------|--------|
| CAS: 1314-23-4 | zirconium dioxide | 10-25% |
| EINECS: 215-227-2 | | |

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
- **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.
- **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, powder or water spray. Fight larger fire with alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters** 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.
Avoid formation of dust.
- **6.2 Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Do not allow to penetrate the ground/soil.
- **6.3 Methods and material for containment and cleaning up:**
Pick up mechanically.
Dispose of the material collected according to regulations.
- **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.
Prevent formation of dust.
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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.

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- 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 facilities: No further data; see item 7.
- 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

1314-23-4 zirconium dioxide (10-25%)

| | |
|--------|---|
| WEL () | Short-term value: 10 mg/m ³ Long-term value: 5 mg/m ³ as Zr |
|--------|---|

94-36-0 dibenzoyl peroxide (< 1.0%)

| | |
|--------|--------------------------------------|
| WEL () | Long-term value: 5 mg/m ³ |
|--------|--------------------------------------|

· DNELs

94-36-0 dibenzoyl peroxide

| | | |
|------------|---|---------------------------------|
| Oral | general population, long term, systemic | 1.65 mg/Kg/d (human) |
| Dermal | general population, long term, systemic | 3.3 mg/Kg/d (human) |
| | worker, long term, systemic | 6.6 mg/Kg/d (human) |
| Inhalative | general population, long term, systemic | 2.9 mg/m ³ (human) |
| | worker, long term, systemic | 11.75 mg/m ³ (human) |

· PNECs

94-36-0 dibenzoyl peroxide

| | |
|-----------------------------------|-----------------------------|
| freshwater | 0.000602 mg/l (not defined) |
| marine water | 0.000602 mg/l (not defined) |
| sediment, freshwater (dry weight) | 0.338 mg/Kg (not defined) |
| sewage treatment plant (STP) | 0.35 mg/l (not defined) |
| soil (dry weight) | 0.0758 mg/Kg (not defined) |

· 8.2 Exposure controls

· Personal protective equipment:

· General protective and hygienic measures: Avoid contact with the skin.

· Respiratory protection: Not necessary if room is well-ventilated.

· Protection of hands: 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.

· For the permanent contact gloves made of the following materials are suitable:

for example:

a glove system comprising 2 gloves with one worn inside the other:
an inner glove made of latex and an outer glove made of polyethylene

· Eye protection: Safety glasses

· Body protection: Light weight protective clothing

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

| | |
|----------------|-------------|
| Form: | Powder |
| Colour: | Light green |
| Odour: | Odourless |

· **pH-value:** Not applicable.

· Change in condition

| | |
|-------------------------------------|---------------|
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | Undetermined. |

· **Flash point:** Not applicable.

· Ignition temperature:

Decomposition temperature: Not determined.

· **Self-igniting:** Not determined.

· **Danger of explosion:** As the product is supplied it is not capable of dust explosion; however enrichment with fine dust causes risk of dust explosion.

· Explosion limits:

| | |
|---------------|-----------------|
| Lower: | Not determined. |
| Upper: | Not determined. |

· **Vapour pressure:** Not applicable.

| | |
|---------------------------|-----------------|
| · Density: | Not determined. |
| · Relative density | Not determined. |
| · Vapour 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. |

· Solvent content:

| | |
|--------------------------|--------|
| Organic solvents: | 0.0 % |
| VOC (EC) | 0.00 % |

Solids content: 100.0 %

· **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity

· 10.2 Chemical stability

· Thermal decomposition / 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.

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· 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

· Acute toxicity:

· LD/LC50 values relevant for classification:

94-36-0 dibenzoyl peroxide

| | | |
|------|------|------------------|
| Oral | LD50 | 5000 mg/kg (rat) |
|------|------|------------------|

| | | |
|------------|----------|------------------|
| Inhalative | LC50/4 h | 24300 mg/l (rat) |
|------------|----------|------------------|

· Primary irritant effect:

· on the skin: No irritant effect.

· on the eye: No irritating effect.

· Sensitisation: Sensitising effect by skin contact is possible by prolonged exposure.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

94-36-0 dibenzoyl peroxide

| | |
|----------|---------------------|
| EC50/48h | 0.11 mg/l (daphnia) |
|----------|---------------------|

| | |
|----------|-------------------|
| EC50/72h | 0.06 mg/l (algae) |
|----------|-------------------|

| | |
|----------|------------------|
| LC50/96h | 0.06 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 Disposal must be made according to official regulations.

· Uncleaned packaging:

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

SECTION 14: Transport information

· 14.1 UN-Number

· ADR, IMDG, IATA Void

· 14.2 UN proper shipping name

· ADR, IMDG, IATA Void

· 14.3 Transport hazard class(es)

· ADR, IMDG, IATA

· Class Void

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| | |
|---|-----------------|
| · 14.4 Packing group · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this 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.

R3 Extreme risk of explosion by shock, friction, fire or other sources of ignition.

R36 Irritating to eyes.

R43 May cause sensitisation by skin contact.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R7 May cause fire.

· **Department issuing MSDS: HH-EHS-CS**· **Abbreviations and acronyms:**

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)

VOC: Volatile Organic Compounds (USA, EU)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1