

1 Identification

- **Product identifier**
- **Trade name:** *Palacos R-, Palacos LV-, Palacos MV-, Palamed-powder*
- **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*
- **Information department:** *sds@heraeus.com*
- **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*

2 Hazard(s) identification

- **Classification of the substance or mixture**
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
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 labeled due to the calculation procedure of international guidelines.
- **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07

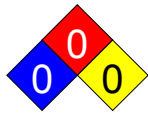
- **Signal word** *Warning*
- **Hazard-determining components of labeling:**
dibenzoyl peroxide
- **Hazard statements**
May cause an allergic skin reaction.
- **Precautionary statements**
*Avoid breathing dust/fume/gas/mist/vapors/spray
Wear protective gloves.
If on skin: Wash with plenty of water.
Specific treatment (see on this label).
Wash contaminated clothing before reuse.
If skin irritation or rash occurs: Get medical advice/attention.*

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- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



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

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Dangerous components:**

| | | |
|---------|--------------------|--------|
| 94-36-0 | dibenzoyl peroxide | < 1.0% |
|---------|--------------------|--------|

- **Non dangerous components:**

| | | |
|-----------|-------------------|--------|
| 1314-23-4 | zirconium dioxide | 10-25% |
|-----------|-------------------|--------|

4 First-aid measures

- **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.
- **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 fire with alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters** No special measures required.
- **Additional information** -

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Avoid formation of dust.
- **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Do not allow to penetrate the ground/soil.
- **Methods and material for containment and cleaning up:**
Pick up mechanically.
Dispose of the collected material according to regulations.
- **Reference to other sections** See Section 8 for information on personal protection equipment.

7 Handling and storage

- **Precautions for safe handling**
Wear protective equipment. Keep unprotected persons away.
Prevent formation of dust.
Ensure good ventilation/exhaustion at the workplace.
- **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:** None.
- **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:**

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

PEL Long-term value: 5 mg/m³
as Zr

REL Short-term value: 10 mg/m³
Long-term value: 5 mg/m³
as Zr

TLV Short-term value: 10 mg/m³
Long-term value: 5 mg/m³
as Zr

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

PEL Long-term value: 5 mg/m³

REL Long-term value: 5 mg/m³

TLV Long-term value: 5 mg/m³

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Avoid contact with the skin.
- **Breathing equipment:** 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

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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

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

| | |
|-----------------|-------------|
| · Form: | Powder |
| · Color: | Light green |
| · Odor: | Odorless |

· **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.

· **Auto 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. |

· **Vapor 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 %

· **Solids content:** 100.0 %

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

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10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
- **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:** No dangerous decomposition products known.

11 Toxicological information

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

· **LD/LC50 values that are 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.
- **Sensitization:** Sensitizing effect by skin contact is possible with prolonged exposure.
- **Additional toxicological information:**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

| | | |
|---------|--------------------|---|
| 94-36-0 | dibenzoyl peroxide | 3 |
|---------|--------------------|---|

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

· **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) |

- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Avoid transfer into the environment.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | Void |
| · DOT, ADR, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · DOT, ADR, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

· **Section 313 (Specific toxic chemical listings):**

94-36-0 dibenzoyl peroxide

· **TSCA (Toxic Substances Control Act):**

Medical devices are exempted from TSCA.

All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

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· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

| | | |
|-----------|--------------------|----|
| 1314-23-4 | zirconium dioxide | A4 |
| 94-36-0 | dibenzoyl peroxide | A4 |

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **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

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves.

If on skin: Wash with plenty of water.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

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

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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.

· **Department issuing SDS:** HH-EHS-CS

· **Date of preparation / last revision** 03/09/2015 / -

· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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

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