


1 Identification

- **Product identifier**
- **Trade name:** *Palacos R+G -, Palacos LV+G -, Palacos MV+G -, Palamed G - 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

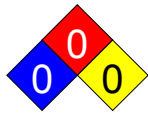
- **Classification of the substance or mixture**
*Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sens. 1 H317 May cause an allergic skin reaction.*
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
*Irritant
May cause sensitisation by inhalation and skin contact.
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**

GHS08
- **Signal word** *Danger*
- **Hazard-determining components of labeling:**
*gentamicin sulfate
dibenzoyl peroxide*
- **Hazard statements**
*May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.*
- **Precautionary statements**
*Do not breathe dust/fume/gas/mist/vapours/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
IF exposed or concerned: Get medical advice/attention.*

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Trade name: Palacos R+G -, Palacos LV+G -, Palacos MV+G -, Palamed G - Powder

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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:**

1405-41-0	gentamicin sulfate	≤ 5.0%
94-36-0	dibenzoyl peroxide	< 1.0%

- **Non dangerous components:**

	methylmethacrylate-methylacrylate-copolymer	50-100%
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; 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. Then consult a doctor.
- **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.

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

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:** 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/m ³ as Zr
REL	Short-term value: 10 mg/m ³ Long-term value: 5 mg/m ³ as Zr
TLV	Short-term value: 10 mg/m ³ Long-term value: 5 mg/m ³ as Zr

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

PEL	Long-term value: 5 mg/m ³
REL	Long-term value: 5 mg/m ³
TLV	Long-term value: 5 mg/m ³

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not necessary if room is well-ventilated.
- **Protection of hands:**
- **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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- **For the permanent contact gloves made of the following materials are suitable:**
For example:
Glove system consisting of two superimposed wearing gloves:
inner glove made of latex, 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

· **Change in condition**

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

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not determined.

· **Ignition temperature:**

Decomposition temperature: Not determined.

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

· **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.

· **Vapor pressure:** Not applicable.

· **Density:**

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:**

VOC content: 0.3 %

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

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.

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Trade name: Palacos R+G -, Palacos LV+G -, Palacos MV+G -, Palamed G - Powder

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

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11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

· **Primary irritant effect:**

· **on the skin:** No irritant effect.

· **on the eye:** No irritating effect.

· **Sensitization:** Sensitization possible through skin contact.

· **Additional toxicological information:**

The product contains antibiotics which may cause allergic effects.

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

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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:** No further relevant information available.

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

· **Behavior in environmental systems:**

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

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

· **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:**

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.

· **Waste disposal key:** None

· **Uncleaned packagings:**

· **Recommendation:** Packaging can be reused or recycled after cleaning.

14 Transport information

· **UN-Number**

· **DOT, ADR, IMDG, IATA** Void

· **UN proper shipping name**

· **DOT, ADR, IMDG, IATA** Void

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Trade name: Palacos R+G -, Palacos LV+G -, Palacos MV+G -, Palamed G - Powder

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· 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.

· **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.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).

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Trade name: Palacos R+G -, Palacos LV+G -, Palacos MV+G -, Palamed G - Powder

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· Hazard pictograms



GHS08

· Signal word *Danger*

· Hazard-determining components of labeling:

gentamicin sulfate
dibenzoyl peroxide

· Hazard statements

May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.

· Precautionary statements

Do not breathe dust/fume/gas/mist/vapours/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
IF exposed or concerned: 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 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
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)
VOC: Volatile Organic Compounds (USA, EU)
Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1