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.
- 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.

(Contd. on page 2)
Trade name: Palacos R+G -, Palacos LV+G -, Palacos MV+G -, Palamed G - Powder

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.
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/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:
    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.

(Contd. on page 4)
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.
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.

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
38.0.10

- Transport hazard class(es)
  DOT, ADR, IMDG, IATA
  Class: Void
- Packing group
  DOT, ADR, IMDG, IATA
  Group: Void
- Environmental hazards:
  Marine pollutant: No
- Special precautions for user
  Not applicable.
- Transport in bulk according to Annex II of MARPOL 73/78 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.
- Cancerogenity 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).
Trade name: Palacos R+G -, Palacos LV+G -, Palacos MV+G -, Palamed G - Powder

- Hazard pictograms

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- Precautionary statements
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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

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