1 Identification

- Product identifier
  - Trade name: Dentalon plus powder

- Application of the substance / the mixture
  Manufacture of dental prothesis

- Details of the supplier of the safety data sheet
  - Manufacturer/Supplier:
    Kulzer GmbH
    Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522

  - Information department:
    Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545
e-mail: customer.servicehkna@kulzer-dental.com

  - Emergency telephone number:
    Emergency CONTACT (24-Hour-Number)
    G BK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

- Classification of the substance or mixture
  The product is not classified according to the Globally Harmonized System (GHS).

- Label elements
  - GHS label elements Void
  - Hazard pictograms Void
  - Signal word Void
  - Hazard statements Void

- Classification system
  - NFPA ratings for USA (scale 0-4)
    Health = 1
    Fire = 1
    Reactivity = 0

  - HMIS-Ratings (Scale 0-4)
    Health = 0
    Fire = 1
    Reactivity = 0

- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

3 Composition/information on ingredients

- Chemical characterization: Mixtures
- Description: Product based on methacrylate copolymerisates

- Dangerous components:
  - 1-Benzyl-5-phenylbarbitursäure 72846-00-5 0-5% Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335

(Contd. on page 2)
4 First-aid measures

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

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.

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**
    - No dangerous substances are released.
    - See Section 8 for information on personal protection equipment.

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.
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:**
    The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
  - **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
  - **Personal protective equipment**
    - **General protective and hygienic measures**
      The usual precautionary measures for handling chemicals should be followed.
    - **Breathing equipment:** Not required.
    - **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
      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 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 through 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:** Not absolutely necessary.
      - **Body protection:** Light weight protective clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Powder
      - **Color:** According to product specification
      - **Odor:** Odorless

### Trade name: Dentalon plus powder

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor threshold</td>
<td>Not determined.</td>
</tr>
<tr>
<td>pH-value</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Change in condition</td>
<td></td>
</tr>
<tr>
<td>Melting point/Melting range</td>
<td>undetermined</td>
</tr>
<tr>
<td>Boiling point/Boiling range</td>
<td>undetermined</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gaseous)</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Ignition temperature</td>
<td></td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Auto igniting</td>
<td>Product is not selfigniting.</td>
</tr>
<tr>
<td>Danger of explosion</td>
<td>Product is not explosive. However, formation of explosive powder/air mixture is possible.</td>
</tr>
<tr>
<td>Explosion limits</td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Upper</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Density at 20 °C (68 °F):</td>
<td>0 g/cm³ (0 lbs/gal)</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapor density</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Solubility in / Miscibility with Water</td>
<td>Insoluble</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Dynamic</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Kinematic</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Solvent content</td>
<td></td>
</tr>
<tr>
<td>Solids content</td>
<td>100.0 %</td>
</tr>
<tr>
<td>Other information</td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

### 10 Stability and reactivity

- **Reactivity**: No further relevant information available.
- **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**: none
11 Toxicalogical information

- Information on toxicalogical effects
  - Acute toxicity:
    - Primary irritant effect:
      - on the skin: No irritant effect.
      - on the eye: No irritating effect.
    - Sensitization: No sensitizing effects known.
  - Additional toxicalogical information:
    The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
    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)
      13463-67-7 Titanium dioxide 3
      8007-18-9 C.I. Pigment Yellow 53 1
    - NTP (National Toxicology Program)
      8007-18-9 C.I. Pigment Yellow 53 K
    - OSHA-Ca (Occupational Safety & Health Administration)
      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.
  - Additional ecological information:
    - General notes:
      Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
  - 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.

- **Uncleaned packagings**
  - **Recommendation**: Packaging can be reused or recycled after cleaning.

14 Transport information

- **UN-Number**
  - DOT, ADR, ADN, IMDG, IATA: Void

- **UN proper shipping name**
  - DOT, ADR, ADN, IMDG, IATA: Void

- **Transport hazard class(es)**
  - DOT, ADR, ADN, IMDG, IATA: 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.

- **Transport/Additional information**
  - -

- **UN "Model Regulation"**: Void

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **SARA Section 355 (extremely hazardous substances)**
    - None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act)**
  - Medical devices are exempted from TSCA.

- **Cancerogenity categories**

<table>
<thead>
<tr>
<th>TLV (Threshold Limit Value established by ACGIH)</th>
</tr>
</thead>
<tbody>
<tr>
<td>13463-67-7</td>
</tr>
<tr>
<td>8007-18-9</td>
</tr>
<tr>
<td>8010-62-0</td>
</tr>
</tbody>
</table>

* (Contd. on page 7)
Safety Data Sheet
acc. to OSHA HCS

Trade name: Dentalon plus powder

- GHS label elements Void
  - Hazard pictograms Void
  - Signal word Void
  - Hazard statements Void
- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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
  - H315 Causes skin irritation.
  - H319 Causes serious eye irritation.
  - H335 May cause respiratory irritation.
- Date of preparation / last revision 06/03/2017 / 2
- 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)
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative
  OSHA: Occupational Safety & Health
  TLV: Threshold Limit Value
  PEL: Permissible Exposure Limit
  REL: Recommended Exposure Limit
  Skin Irrit. 2: Skin corrosion/irritation – Category 2
  Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
  STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- * Data compared to the previous version altered.