1 Identification

- **Product identifier**
  - **Trade name:** HeraCeram, HeraCeramSun paste opaque
    - Pre-Opaque, Basic-Opaque, Intensive-Opaque
  - **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)
    GBK/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 = 0
    Fire = 1
    Reactivity = 0
  - **HMIS-Ratings (Scale 0-4)**
    
    HEALTH 0 Health = 0
    FIRE 1 Fire = 1
    REACTIVITY 0 Reactivity = 0

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

3 Composition/information on ingredients

- **Chemical characterization:** Mixtures
  - **Description:**
    - **Dangerous components:**
      110-63-4 butane-1,4-diol Acute Tox. 4, H302 10-25%
4 First-aid measures

· Description of first aid measures
  · General information
    Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
  · After skin contact Generally the product does not irritate the skin.
  · After eye contact Rinse opened eye for several minutes under running water.
  · After swallowing
    Rinse out mouth and then drink plenty of water.
    Drink copious amounts of water and provide fresh air. Immediately call a doctor.
    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.
  · Use fire fighting measures that suit the environment.
  · Special hazards arising from the substance or mixture
    No further relevant information available.
  · Advice for firefighters
  · Protective equipment: No special measures required.
  · Additional information -

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:
  · Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
  · Dispose contaminated material as waste according to item 13.
· 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.
    - **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**: 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**: 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 cannot 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: Pasty
      · Color: Different according to coloring
    · Odor: Characteristic
    · Odor threshold: Not determined.
  · pH-value: Not determined.

· Change in condition
  · Melting point/Melting range: undetermined
  · Boiling point/Boiling range: 230 °C (446 °F)

· Flash point: 134 °C (273 °F)

· Flammability (solid, gaseous) Not applicable.

· Ignition temperature: 385 °C (725 °F)

· Decomposition temperature: Not determined.

· Auto igniting: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

· Explosion limits:
  · Lower: Not determined.
  · Upper: Not determined.

· Vapor pressure: Not determined.

· Density at 20 °C (68 °F): 1.900 g/cm³ (15.856 lbs/gal)
  · Relative density: Not determined.
  · Vapor density: Not determined.
  · Evaporation rate: Not determined.

· Solubility in / Miscibility with
  · Water: Not miscible or difficult to mix

· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:
  · dynamic: Not determined.
  · kinematic: Not determined.

· Solvent content:
  · Solids content: 30.0 %

· Other information No further relevant information available.

10 Stability and reactivity

· Reactivity No further relevant information available.

· Possibility of hazardous reactions No dangerous reactions known
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acc. to OSHA HCS

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- **Conditions to avoid**: No further relevant information available.
- **Incompatible materials**: No further relevant information available.
- **Hazardous decomposition products**: None

### 11 Toxicological information

#### Information on toxicological effects

**Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**
  - **110-63-4 butane-1,4-diol**
  - Oral LD50 1525 mg/kg (rat)

**Primary irritant effect:**

- **on the skin**: No irritant effect.
- **on the eye**: No irritating effect.

**Sensitization**: No sensitizing effects known.

**Additional toxicological 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)**
    None of the ingredients is listed.
  - **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**: 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.
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· Other adverse effects No further relevant information available.

13 Disposal considerations
· Waste treatment methods
  · Recommendation Smaller quantities can be disposed of with household waste.
· Uncleaned packagings:
  · Recommendation: Disposal must be made according to official regulations.

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
  · 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.
· 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.
· Cancerogenity categories
  · TLV (Threshold Limit Value established by ACGIH) None of the ingredients is listed.
  · GHS label elements Void
    · Hazard pictograms Void
    · Signal word Void
    · Hazard statements Void

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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
  - H302 Harmful if swallowed.
- Date of preparation / last revision: 06/03/2017 / 3
- 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
  - 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
  - Acute Tox. 4: Acute toxicity – Category 4
- * Data compared to the previous version altered.