SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   • Trade name: HeraCeram, HeraCeramSun paste opaque
     - Pre-Opaque, Basic-Opaque, Intensive-Opaque

1.2 Relevant identified uses of the substance or mixture and uses advised against
   No further relevant information available.

1.3 Details of the supplier of the safety data sheet
   • Manufacturer/Supplier:
     Kulzer GmbH
     Leipziger Straße 2, 63450 Hanau (Germany)
     Tel.: +49 (0)800 4372522
   • Informing department: E-Mail: msds@kulzer-dental.com

1.4 Emergency telephone number:
   Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   • Classification according to Regulation (EC) No 1272/2008
     STOT SE 3 H336 May cause drowsiness or dizziness.

2.2 Label elements
   • Labelling according to Regulation (EC) No 1272/2008
     The product is classified and labelled according to the CLP regulation.
     • Hazard pictograms

   GHS07

   • Signal word Warning

   • Hazard-determining components of labelling:
     butane-1,4-diol

   • Hazard statements
     H336 May cause drowsiness or dizziness.

   • Precautionary statements
     P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
     P271 Use only outdoors or in a well-ventilated area.
     P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
     P312 Call a POISON CENTER/doctor if you feel unwell.
     P405 Store locked up.
     P403+P233 Store in a well-ventilated place. Keep container tightly closed.

2.3 Other hazards
   • Results of PBT and vPvB assessment
     • PBT: Not applicable.
**SECTION 3: Composition/information on ingredients**

- **3.2 Chemical characterisation: Mixtures**
  - **Description:**
  - **Dangerous components:**
    - CAS: 110-63-4
    - EINECS: 203-786-5
    - butane-1,4-diol
    - Acute Tox. 4, H302; STOT SE 3, H336
    - 10-25%
  - **Additional information** For the wording of the listed hazard phrases refer to section 16.

**SECTION 4: First aid measures**

- **4.1 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** The product is not skin irritating.
    - **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. Instantly call for doctor. In case of persistent symptoms consult doctor.
  - **4.2 Most important symptoms and effects, both acute and delayed**
    - No further relevant information available.
  - **4.3 Indication of any immediate medical attention and special treatment needed**
    - No further relevant information available.

**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
  - **Suitable extinguishing agents**
    - CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
    - Use fire fighting measures that suit the environment.
  - **5.2 Special hazards arising from the substance or mixture**
    - No further relevant information available.
  - **5.3 Advice for firefighters**
    - **Protective equipment:** No special measures required.
    - **Additional information**

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**
  - Not required.
- **6.2 Environmental precautions:**
  - No special measures required.
- **6.3 Methods and material for containment and cleaning up:**
  - Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
  - Dispose of contaminated material as waste according to item 13.
SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
  - **Information about protection against explosions and fires:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
  - **Storage**
    - **Requirements to be met by storerooms and containers:** No special requirements.
    - **Information about storage in one common storage facility:** Not required.
    - **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
  - **Components with critical 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 compilation were used as basis.
- **8.2 Exposure controls**
  - **Personal protective equipment**
    - **General protective and hygienic measures**
      The usual precautionary measures should be adhered to in handling the chemicals.
    - **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 can not be calculated in advance and has therefore to be checked prior to the application.
    - **Penetration time of glove material**
      The exact break trough 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 neccessary
**Trade name:** HeraCeram, HeraCeramSun paste opaque

- **Body protection:** Light weight protective clothing

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

- **General Information**
  - **Appearance:** Pasty
  - **Colour:** Different according to colour
  - **Smell:** Characteristic
  - **Odour threshold:** Not determined.
  - **pH-value:** Not determined.

- **Change in condition**
  - **Melting point/Melting range:** Not determined
  - **Boiling point/Boiling range:** 230 °C

- **Flash point:** 134 °C

- **Inflammability (solid, gaseous)** Not applicable.

- **Ignition temperature:** 385 °C

- **Decomposition temperature:** Not determined.

- **Self-inflammability:** Product is not selfigniting.

- **Danger of explosion:** Product is not explosive.

- **Critical values for explosion:**
  - **Lower:** Not determined.
  - **Upper:** Not determined.

- **Steam pressure:** Not determined.

- **Density at 20 °C**
  - **Relative density:** Not determined.
  - **Vapour 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:**
  - **VOC EU**
  - **Solids content:** 30.0 %
Trade name: HeraCeram, HeraCeramSun paste opaque

9.2 Other information
No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity
No further relevant information available.

10.2 Chemical stability
- Conditions to be avoided: No decomposition if used and stored according to specifications.

10.3 Possibility of hazardous reactions
No dangerous reactions known

10.4 Conditions to avoid
No further relevant information available.

10.5 Incompatible materials
No further relevant information available.

10.6 Hazardous decomposition products
None

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity
Based on available data, the classification criteria are not met.

LD/LC50 values that are relevant for classification:

110-63-4 butane-1,4-diol

Oral LD50 1525 mg/kg (rat)

- Primary irritant effect:
  - Skin corrosion/irritation Based on available data, the classification criteria are not met.
  - Serious eye damage/irritation Based on available data, the classification criteria are not met.

- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

- CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
  - Germ cell mutagenicity Based on available data, the classification criteria are not met.
  - Carcinogenicity Based on available data, the classification criteria are not met.
  - Reproductive toxicity Based on available data, the classification criteria are not met.

- STOT-single exposure
May cause drowsiness or dizziness.

- STOT-repeated exposure Based on available data, the classification criteria are not met.

- Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity
- Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability
No further relevant information available.

12.3 Bioaccumulative potential
No further relevant information available.

12.4 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 bodies or sewage system.

12.5 Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.
Trade name: HeraCeram, HeraCeramSun paste opaque

12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
- Recommendation Smaller quantities can be disposed with household garbage.
- European waste catalogue
  18 01 06 chemicals consisting of or containing dangerous substances
- Uncleaned packagings:
  - Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN-Number
- ADR, ADN, IMDG, IATA Void

14.2 UN proper shipping name
- ADR, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)
- ADR, ADN, IMDG, IATA
  - Class Void

14.4 Packing group
- ADR, IMDG, IATA Void

14.5 Environmental hazards:
- Marine pollutant: No

14.6 Special precautions for user Not applicable.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.
  - Transport/Additional information: -
  - UN “Model Regulation”: Void

SECTION 15: Regulatory information

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

SECTION 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.
  H336 May cause drowsiness or dizziness.
## 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
- **IATA**: International Air Transport Association
- **GHS**: Globally Harmonised System of Classification and Labelling of Chemicals
- **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)
- **VOCV**: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
- **LC50**: Lethal concentration, 50 percent
- **LD50**: Lethal dose, 50 percent
- **PBT**: Persistent, Bioaccumulative and Toxic
- **vPvB**: very Persistent and very Bioaccumulative
- **Acute Tox. 4**: Acute toxicity – Category 4
- **STOT SE 3**: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.