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

1.1 Product identifier
   - Trade name: HeraCeram opaque liquid

1.2 Relevant identified uses of the substance or mixture and uses advised against
   - Application of the substance / the mixture: Manufacture of dental prothesis

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
     The product is not classified according to the CLP regulation.

2.2 Label elements
   - Labelling according to Regulation (EC) No 1272/2008 Void
     - Hazard pictograms Void
     - Signal word Void
     - Hazard statements Void

2.3 Other hazards
   - Results of PBT and vPvB assessment
     - PBT: Not applicable.
     - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures
   - Description: -

   Dangerous components:
   - CAS: 64-17-5
   - EINECS: 200-578-6
   - Reg.nr.: 2119457610-43-xxxx
   - ethanol Flam. Liq. 2, H225 0-5%

   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 No special measures required.
   - 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.
   - In case of persistent symptoms consult doctor.

(Contd. on page 2)
Trade name: HeraCeram opaque liquid

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.
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: Dilute with much water.
6.3 Methods and material for containment and cleaning up:
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
6.4 Reference to other sections
No dangerous materials are released.
See Section 8 for information on personal protection equipment.

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

- Additional information about design of technical systems: No further data; see item 7.
8.1 Control parameters
- Components with critical values that require monitoring at the workplace:
  64-17-5 ethanol
  OELV (O) 1900 mg/m³, 1000 ppm

(Contd. on page 3)
Trade name: HeraCeram opaque liquid

- **DNELs**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Exposure Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 ethanol</td>
<td>Oral ge.pop., l.te, syst.</td>
<td>87 mg/Kg (nd)</td>
</tr>
<tr>
<td></td>
<td>Dermal ge.pop., l.te, syst.</td>
<td>343 mg/Kg/d (nd)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>950 mg/Kg/d (nd)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>206 mg/Kg/d (nd)</td>
</tr>
<tr>
<td></td>
<td>Inhalative ge.pop., l.te, syst.</td>
<td>1900 mg/m3 (nd)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1900 mg/m3 (nd)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>950 mg/m3 (nd)</td>
</tr>
</tbody>
</table>

- **PNECs**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Exposure Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 ethanol</td>
<td>freshwater</td>
<td>0.96 mg/l (nd)</td>
</tr>
<tr>
<td></td>
<td>marine water</td>
<td>0.79 mg/l (nd)</td>
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<tr>
<td></td>
<td>STP</td>
<td>580 mg/l (nd)</td>
</tr>
<tr>
<td></td>
<td>sedim., dw, fre.wat.</td>
<td>3.6 mg/Kg (nd)</td>
</tr>
<tr>
<td></td>
<td>soil,dw</td>
<td>0.63 mg/Kg (nd)</td>
</tr>
</tbody>
</table>

- 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 cannot 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 necessary

- **Body protection**: Light weight protective clothing
### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:** Fluid
    - **Form:** Fluid
    - **Colour:** Colourless
    - **Smell:** Characteristic
    - **Odour threshold:** Not determined.
  - **pH-value:** Not determined.
  - **Change in condition**
    - **Melting point/Melting range:** Not determined
    - **Boiling point/Boiling range:** 98 °C
  - **Flash point:** Not applicable
  - **Inflammability (solid, gaseous)** Not applicable.
  - **Ignition temperature:** Product is not selfigniting.
  - **Decomposition temperature:** Not determined.
  - **Self-inflammability:** Product is not explosive.
  - **Critical values for explosion:**
    - **Lower:** Not determined.
    - **Upper:** Not determined.
  - **Steam pressure at 20 °C:** 23 hPa
  - **Density at 20 °C:** 0.980 g/cm²
    - **Relative density:** Not determined.
    - **Vapour density:** Not determined.
    - **Evaporation rate:** Not determined.
  - **Solubility in / Miscibility with**
    - **Water:** Fully miscible
  - **Partition coefficient (n-octanol/water):** Not determined.
  - **Viscosity:**
    - **dynamic:** Not determined.
    - **kinematic:** Not determined.
  - **Solvent content:**
    - **Water:** 96.0 %

### 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.
Trade name: HeraCeram opaque liquid

- **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:**
    - Ethanol:
      - Oral LD50: 6200 mg/kg (rat)
      - Inhalative LC50/4 h: 95.6 mg/l (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 Based on available data, the classification criteria are not met.
  - 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.
- **12.5 Results of PBT and vPvB assessment**
  - PBT: Not applicable.
  - vPvB: Not applicable.
- **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 packaging**:
    - **Recommendation**: Disposal must be made according to official regulations.
Trade name: HeraCeram opaque liquid

- **Recommended cleaning agent:** Water, if necessary with cleaning agent.

**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**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - National regulations
    - Water hazard class: Generally not hazardous for water.
- **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**
  - H225 Highly flammable liquid and vapour.
- **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
Trade name: HeraCeram opaque liquid

CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2

* Data compared to the previous version altered.