



**Safety data sheet  
according to 1907/2006/EC, Article 31**

Printing date 02.08.2022

Version number 5 (replaces version 1)

Revision: 02.08.2022

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

- **1.1 Product identifier**
  - Trade name: **HeraCeram Pre Opaque, HeraCeram Sun Basic Opaque**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**


No further relevant information available.

  - **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](mailto: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 GB 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.  
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P312 Call a POISON CENTER/doctor if you feel unwell.
- **2.3 Other hazards -**
    - **Results of PBT and vPvB assessment**
      - **PBT:** Not applicable.
      - **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

- **3.2 Mixtures**
  - **Description:** -

· **Dangerous components:**

CAS: 110-63-4 EINECS: 203-786-5	butane-1,4-diol	Acute Tox. 4, H302; STOT SE 3, H336	25-50%
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· **Additional information** For the wording of the listed hazard phrases refer to section 16. (Contd. of page 1)

#### **SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
  - **After inhalation** Supply fresh air; consult doctor in case of symptoms.
  - **After skin contact**  
Instantly 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 doctor.
  - **After swallowing**  
Rinse out mouth and then drink plenty of water.  
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**  
CO<sub>2</sub>, 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**  
Formation of toxic gases is possible during heating or in case of fire.
- **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**  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- **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.
- **6.4 Reference to other sections**  
No dangerous materials are released.  
See Section 7 for information on safe handling  
See Section 8 for information on personal protection equipment.  
See Section 13 for information on disposal.  
-

#### **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** Ensure good ventilation/exhaustion at the workplace.
  - **Information about protection against explosions and fires:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.

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- **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.  
Not required.

    - **Additional information:** The lists that were valid during the compilation were used as basis.
- **8.2 Exposure controls**
  - **Appropriate engineering controls** No further data; see item 7.
  - **Individual protection measures, such as personal protective equipment**
    - **General protective and hygienic measures**

Keep away from foodstuffs, beverages and food.  
Wash hands during breaks and at the end of the work.
    - **Breathing equipment:** Use breathing protection in case of insufficient ventilation.
    - **Hand protection**

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/face protection** Safety glasses
    - **Body protection:** Light weight protective clothing

**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Physical state** Fluid
    - **Colour:** Yellow  
Orange
    - **Smell:** Characteristic
    - **Odour threshold:** Not determined.
    - **Melting point/freezing point:** Not determined

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<ul style="list-style-type: none"><li>· <b>Boiling point or initial boiling point and boiling range</b></li><li>· <b>Flammability</b></li><li>· <b>Lower and upper explosion limit</b><ul style="list-style-type: none"><li>· Lower:</li><li>· Upper:</li></ul></li><li>· <b>Flash point:</b></li><li>· <b>Decomposition temperature:</b></li><li>· <b>SADT</b></li><li>· <b>pH</b></li><li>· <b>Viscosity:</b><ul style="list-style-type: none"><li>· Kinematic viscosity</li><li>· dynamic:</li></ul></li><li>· <b>Solubility</b><ul style="list-style-type: none"><li>· Water:</li></ul></li><li>· <b>Partition coefficient n-octanol/water (log value)</b></li><li>· <b>Steam pressure:</b></li><li>· <b>Density and/or relative density</b><ul style="list-style-type: none"><li>· Density at 20 °C</li><li>· Relative density</li><li>· Vapour density</li></ul></li></ul>	<p>230 °C (110-63-4 butane-1,4-diol) Not applicable. Not determined. Not determined. 112 °C (110-63-4 butane-1,4-diol) Not determined. Not determined. Not determined. Not determined. Not determined. Not determined. Fully miscible Not determined. Not determined. 1.2 g/cm<sup>3</sup> Not determined. Not determined.</p>
<ul style="list-style-type: none"><li>· <b>9.2 Other information</b></li><li>· <b>Appearance:</b><ul style="list-style-type: none"><li>· Form:</li></ul></li><li>· <b>Important information on protection of health and environment, and on safety.</b><ul style="list-style-type: none"><li>· Self-inflammability:</li><li>· Explosive properties:</li></ul></li><li>· <b>Change in condition</b><ul style="list-style-type: none"><li>· Evaporation rate</li></ul></li></ul>	<p>No further relevant information available. Pasty Product is not selfigniting. Product is not explosive. Not determined. Not determined.</p>
<ul style="list-style-type: none"><li>· <b>Information with regard to physical hazard classes</b><ul style="list-style-type: none"><li>· Explosives</li><li>· Flammable gases</li><li>· Aerosols</li><li>· Oxidising gases</li><li>· Gases under pressure</li><li>· Flammable liquids</li><li>· Flammable solids</li><li>· Self-reactive substances and mixtures</li><li>· Pyrophoric liquids</li><li>· Pyrophoric solids</li><li>· Self-heating substances and mixtures</li><li>· Substances and mixtures, which emit flammable gases in contact with water</li><li>· Oxidising liquids</li><li>· Oxidising solids</li><li>· Organic peroxides</li><li>· Corrosive to metals</li></ul></li></ul>	<p>Void Void</p>

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· **Desensitised explosives**

Void

**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
  - **Additional information:** -

**SECTION 11: Toxicological information**

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
  - **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 1,500 mg/kg (rat)

Dermal LD50 >2,000 mg/kg (rat)

**81-13-0 Dexpanthenol**

Oral LD50 >10,000 mg/kg (rat) (OECD 401)

Dermal LD50 >2,000 mg/kg (rat) (EU B.3)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **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.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

**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 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

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· **12.7 Other adverse effects**

· **Additional ecological information:**

· **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

**SECTION 13: Disposal considerations**

· **13.1 Waste treatment methods**

· **Recommendation**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

· **Uncleaned packagings:**

· **Recommendation:**

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

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

**SECTION 14: Transport information**

· **14.1 UN number or ID number**

· **ADR, 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 Maritime transport in bulk according to IMO instruments**

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**

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

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· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out. (Contd. of page 6)

**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:**

*SADT: Self Accelerating Decomposition Temperature*

*ADR: Accord relatif au transport international 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)*

*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.**