



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

Printing date 28.06.2023

Version number 6 (replaces version 5)

Revision: 28.06.2023

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

- **1.1 Product identifier**
  - Trade name: **HeraCeram Pasteopaque, HeraCeramSun Pasteopaque**
- **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	butane-1,4-diol	≥20-≤50%
EINECS: 203-786-5	Acute Tox. 4, H302: STOT SE 3, H336 ATE: LD50 oral: 1,500 mg/kg	

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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** 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.  
Drink copious amounts of water and provide fresh air. Instantly call for 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**  
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.  
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** No special measures required.
  - **Information about protection against explosions and fires:** No special measures required.

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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 section 7.
  - **Individual protection measures, such as personal protective equipment**
    - **General protective and hygienic measures**

Wash hands during breaks and at the end of the work.
    - **Breathing equipment:** Not required.
    - **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:** White  
Pink  
Brown  
Blue
    - **Smell:** Characteristic
    - **Odour threshold:** Not determined.

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· <b>Melting point/freezing point:</b>	Not determined
· <b>Boiling point or initial boiling point and boiling range</b>	230 °C (110-63-4 butane-1,4-diol)
· <b>Flammability</b>	Not applicable.
· <b>Lower and upper explosion limit</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Flash point:</b>	134 °C
· <b>Auto-ignition temperature:</b>	385 °C
· <b>Decomposition temperature:</b>	Not determined.
· <b>SADT</b>	
· <b>pH</b>	Mixture is non-soluble (in water).
· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not determined.
· <b>Kinematic viscosity</b>	
· <b>dynamic:</b>	Not determined.
· <b>Solubility</b>	
· <b>Water:</b>	Not miscible or difficult to mix
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Steam pressure:</b>	Not determined.
· <b>Vapour pressure:</b>	
· <b>Density and/or relative density</b>	
· <b>Density at 20 °C</b>	1.9 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.

· <b>9.2 Other information</b>	No further relevant information available.
· <b>Appearance:</b>	
· <b>Form:</b>	Pasty
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Self-inflammability:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive. Not determined.
· <b>Solvent content:</b>	
· <b>VOC EU</b>	g/l
· <b>Solids content:</b>	30.0 %
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not determined.

· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void

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- |  |      |
|--|------|
| · <b>Substances and mixtures, which emit flammable gases in contact with water</b> | Void |
| · <b>Oxidising liquids</b>   | Void |
| · <b>Oxidising solids</b>  | Void |
| · <b>Organic peroxides</b>   | Void |
| · <b>Corrosive to metals</b>   | Void |
| · <b>Desensitised explosives</b>   | 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)

- **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.
- **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.

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- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
For information on endocrine disrupting properties see section 11.
- **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.

**SECTION 14: Transport information**

- |   |                 |
|---|-----------------|
| · <b>14.1 UN number or ID number</b><br>· ADR, ADN, IMDG, IATA                | Void            |
| · <b>14.2 UN proper shipping name</b><br>· ADR, ADN, IMDG, IATA               | Void            |
| · <b>14.3 Transport hazard class(es)</b><br>· ADR, ADN, IMDG, IATA<br>· Class | Void            |
| · <b>14.4 Packing group</b><br>· ADR, IMDG, IATA                              | Void            |
| · <b>14.5 Environmental hazards:</b><br>· Marine pollutant:                   | No              |
| · <b>14.6 Special precautions for user</b>                                    | Not applicable. |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b>         | Not applicable. |
| · <b>Transport/Additional information:</b>                                    | -               |
| · <b>UN "Model Regulation":</b>   | Void            |

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.

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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)

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.**