



**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

· **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	<i>butane-1,4-diol</i>	Acute Tox. 4, H302; STOT SE 3, H336	25-50%
EINECS: 203-786-5			

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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**
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**
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">· Boiling point or initial boiling point and boiling range· Flammability· Lower and upper explosion limit<ul style="list-style-type: none">· Lower:· Upper:· Flash point:· Decomposition temperature:· SADT· pH· Viscosity:<ul style="list-style-type: none">· Kinematic viscosity· dynamic:· Solubility<ul style="list-style-type: none">· Water:· Partition coefficient n-octanol/water (log value)· Steam pressure:· Density and/or relative density<ul style="list-style-type: none">· Density at 20 °C· Relative density· Vapour density	<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/cm³ Not determined. Not determined.</p>
<ul style="list-style-type: none">· 9.2 Other information· Appearance:<ul style="list-style-type: none">· Form:· Important information on protection of health and environment, and on safety.<ul style="list-style-type: none">· Self-inflammability:· Explosive properties:· Change in condition<ul style="list-style-type: none">· Evaporation rate	<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">· Information with regard to physical hazard classes<ul style="list-style-type: none">· Explosives· Flammable gases· Aerosols· Oxidising gases· Gases under pressure· Flammable liquids· Flammable solids· Self-reactive substances and mixtures· Pyrophoric liquids· Pyrophoric solids· Self-heating substances and mixtures· Substances and mixtures, which emit flammable gases in contact with water· Oxidising liquids· Oxidising solids· Organic peroxides· Corrosive to metals	<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.**