



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

Printing date 28.07.2022

Version number 3

Revision: 28.07.2022

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

· **1.1 Product identifier**

· Trade name: **HeraCeram**

· -

*Opaque, Dentine, Incisal, Transpa, Increaser, Enhancer, Mask, Margin, Gingiva, Correction, Secondary Dentine, Mamelon Dentine, Value, Opal Incisal, Opal Transpa, Stains universal powder, Glaze universal*

· **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**

*The product is not classified, according to the GB 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 Mixtures**

· **Dangerous components:** *Void*

**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. Then consult doctor.*

· **After swallowing**

*Rinse out mouth and then drink plenty of water.*

*In case of persistent symptoms consult doctor.*

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· **4.2 Most important symptoms and effects, both acute and delayed**

*No further relevant information available.*

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- **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.
- **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:**  
Do not allow product to reach sewage system or water bodies.  
Do not allow to enter the ground/soil.
- **6.3 Methods and material for containment and cleaning up:** Collect mechanically.
- **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** Prevent formation of dust.
  - **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.  
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**  
The usual precautionary measures should be adhered to in handling the chemicals.

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· **Breathing equipment:**

Use a mask with particle filter in case of dust generation.  
Filter P1.

· **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.

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** Protective goggles are recommended.

· **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**

Solid.

· **Colour:**

According to product specification

· **Smell:**

Odourless

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

900 °C

>750 °C

· **Boiling point or initial boiling point and boiling range**

Not determined

· **Flammability**

Not determined.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

Not applicable

· **Decomposition temperature:**

Not determined.

· **SADT**

· **pH**

Not applicable.

· **Viscosity:**

· **Kinematic viscosity**

Not applicable.

· **dynamic:**

Not applicable.

· **Solubility**

· **Water:**

Insoluble

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Steam pressure:**

Not applicable.

· **Density and/or relative density**

· **Density at 20 °C**

2.5 g/cm<sup>3</sup>

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· <b>Relative density</b>	Not determined.
· <b>Settled apparent density at 20 °C</b>	830 kg/m <sup>3</sup>
· <b>Vapour density</b>	Not applicable.
· <b>9.2 Other information</b>	No further relevant information available.
· <b>Appearance:</b>	
· <b>Form:</b>	Powder
· <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>Solids content:</b>	100.0 %
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not applicable.
· <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
· <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.
  - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.

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- **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** 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.
- **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**

For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects** No further relevant information available.

### 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:** Packaging can be reused or recycled after cleaning.

### SECTION 14: Transport information

- |   |      |
|---|------|
| · <b>14.1 UN number or ID number</b> <ul style="list-style-type: none"><li>· <b>ADR, ADN, IMDG, IATA</b></li></ul>                            | Void |
| · <b>14.2 UN proper shipping name</b> <ul style="list-style-type: none"><li>· <b>ADR, ADN, IMDG, IATA</b></li></ul>                           | Void |
| · <b>14.3 Transport hazard class(es)</b> <ul style="list-style-type: none"><li>· <b>ADR, ADN, IMDG, IATA</b></li><li>· <b>Class</b></li></ul> | Void |
| · <b>14.4 Packing group</b> <ul style="list-style-type: none"><li>· <b>ADR, IMDG, IATA</b></li></ul>  | Void |

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- |   |                 |
|---|-----------------|
| · <b>14.5 Environmental hazards:</b>                                  |                 |
| · <b>Marine pollutant:</b>  | 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**
  - **Directive 2012/18/EU**
    - **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.

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)  
ICAO: International Civil Aviation Organisation  
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)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative

- **\* Data compared to the previous version altered.**



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**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	<i>butane-1,4-diol</i>	Acute Tox. 4, H302; STOT SE 3, H336	≥20-≤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** 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 item 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>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>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>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
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void

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

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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.

**SECTION 14: Transport information**

· **14.1 UN number or ID 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 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**

No further relevant information available.

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· **Directive 2012/18/EU**

· **Other regulations, limitations and prohibitive regulations**

· **Substances of very high concern (SVHC) according to REACH, Article 57**

872-50-4 1-methyl-2-pyrrolidone

· **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:**

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

SVHC: Substances of Very High Concern

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.**



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Printing date 02.08.2022

Version number 4 (replaces version 3)

Revision: 02.08.2022

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

· **1.1 Product identifier**

· Trade name: **HeraCeram NP-Primer NICHT Final nur für RMA**

· **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

Eye Irrit. 2 H319 Causes serious eye irritation.

· **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 statements

H319 Causes serious eye irritation.

· Precautionary statements

P280

Wear protective gloves / eye protection.

P337+P313 If eye irritation persists: Get medical advice/attention.

· **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: 584-03-2	butane-1,2-diol	Eye Irrit. 2, H319	≥10-≤50%
EINECS: 209-527-2			
Reg.nr.: 01-2120762066-55-xxxx			



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**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
  - **General information** No special measures required.
  - **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.
- **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**  
Avoid contact with eyes and skin.  
Wear protective clothing.
- **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.

**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:** 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.

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**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**

Wash hands during breaks and at the end of the work.

Avoid contact with the eyes and skin.

· **Breathing equipment:** Not necessary if room is well-ventilated.

· **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** Tightly sealed 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:**

Orange

· **Smell:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Not determined

· **Boiling point or initial boiling point and boiling range**

192 °C (584-03-2 butane-1,2-diol)

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

2.4 Vol % (584-03-2 butane-1,2-diol)

· **Upper:**

13.5 Vol % (584-03-2 butane-1,2-diol)

· **Flash point:**

93 °C (584-03-2 butane-1,2-diol)

· **Ignition temperature:**

390 °C (584-03-2 butane-1,2-diol)

· **Decomposition temperature:**

Not determined.

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· <b>SADT</b>	
· pH at 20 °C	6-7
· <b>Viscosity:</b>	
· Kinematic viscosity	Not determined.
· dynamic:	Not determined.
· <b>Solubility</b>	
· Water:	Fully miscible
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Steam pressure:</b>	Not determined.
· <b>Density and/or relative density</b>	
· Density at 20 °C	1.9 g/cm <sup>3</sup>
· Relative density	Not determined.
· Vapour density	Not determined.

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

· <b>Information with regard to physical hazard classes</b>	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· 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.

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- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None
- **Additional information:** -

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**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:**

**584-03-2 butane-1,2-diol**

Oral	LD50	>2,000 mg/kg (rat) (OECD 420)
Inhalative	LC50/4 h	370 mg/l (rat)

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

· **Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information**

- **12.1 Toxicity**

· **Aquatic toxicity:**

**584-03-2 butane-1,2-diol**

EC50/48h	500 mg/l (daphnia)
LC50/96h	>10,000 mg/l (fish)

- **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.
- **12.7 Other adverse effects**
  - **Additional ecological information:**
    - **General notes:** Avoid transfer into the environment.

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**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.

**SECTION 14: Transport information**

· **14.1 UN number or ID 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 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**

No further relevant information available.

· **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**

H319 Causes serious eye irritation.

· **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

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*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*  
*Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*

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**\* Data compared to the previous version altered.**

GB



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Printing date 02.08.2022

Version number 3

Revision: 02.08.2022

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

· **1.1 Product identifier**

· Trade name: **HeraCeram modeling liquid**

· - Modeling Liquid ML / MLS

· **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** Auxiliary for 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**

The product is not classified, according to the GB 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 Mixtures**

· **Description:** -

· **Dangerous components:** Void

· **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.

· **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.

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**Trade name: HeraCeram modeling liquid**

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**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.
- **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).
- **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**

- **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**  
The usual precautionary measures should be adhered to in handling the chemicals.
    - **Breathing equipment:** Not required.
    - **Hand protection**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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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** 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**

- |   |  |
|---|--|
| · <b>Physical state</b>   | Fluid  |
| · <b>Colour:</b>  | Colourless   |
| · <b>Smell:</b>   | Odourless  |
| · <b>Odour threshold:</b>   | Not determined.  |
| · <b>Melting point/freezing point:</b>                            | Not determined   |
| · <b>Boiling point or initial boiling point and boiling range</b> | 100 °C (7732-18-5 water, distilled, conductivity or of similar purity) |
| · <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>   | Not applicable   |
| · <b>Decomposition temperature:</b>                               | Not determined.  |
| · <b>SADT</b>   |  |
| · <b>pH</b>   | Not determined.  |
| · <b>Viscosity:</b>   |  |
| · <b>Kinematic viscosity</b>                                      | Not determined.  |
| · <b>dynamic:</b>   | Not determined.  |
| · <b>Solubility</b>   |  |
| · <b>Water:</b>   | Fully miscible   |
| · <b>Partition coefficient n-octanol/water (log value)</b>        | Not determined.  |
| · <b>Steam pressure at 20 °C:</b>                                 | 23 hPa   |
| · <b>Density and/or relative density</b>                          |  |
| · <b>Density at 20 °C</b>   | 1 g/cm <sup>3</sup>  |
| · <b>Relative density</b>   | Not determined.  |
| · <b>Vapour density</b>   | Not determined.  |

· **9.2 Other information**

No further relevant information available.

- **Appearance:**
- **Form:**

Fluid

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**· Important information on protection of health and environment, and on safety.**

- **Self-inflammability:** Product is not selfigniting.
- **Explosive properties:** Product is not explosive.  
Not determined.
  
- **Solvent content:**
- **VOC EU** g/l
- **Change in condition**
- **Evaporation rate** Not determined.

**· Information with regard to physical hazard classes**

- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void
- **Flammable solids** Void
- **Self-reactive substances and mixtures** Void
- **Pyrophoric liquids** Void
- **Pyrophoric solids** Void
- **Self-heating substances and mixtures** Void
- **Substances and mixtures, which emit flammable gases in contact with water** Void
- **Oxidising liquids** Void
- **Oxidising solids** Void
- **Organic peroxides** Void
- **Corrosive to metals** Void
- **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.
  - **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** Based on available data, the classification criteria are not met.

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- **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**  
For information on endocrine disrupting properties see section 11.
- **12.7 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.
- **Uncleaned packagings:**
  - **Recommendation:** Disposal must be made according to official regulations.

**SECTION 14: Transport information**

- |   |                 |
|---|-----------------|
| · <b>14.1 UN number or ID number</b><br>· <b>ADR, ADN, IMDG, IATA</b>                       | Void            |
| · <b>14.2 UN proper shipping name</b><br>· <b>ADR, ADN, IMDG, IATA</b>                      | Void            |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | Void            |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | Void            |
| · <b>14.5 Environmental hazards:</b><br>· <b>Marine pollutant:</b>                          | 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>  | -               |

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· **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**
    - **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.*

· **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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

- **\* Data compared to the previous version altered.**



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

· **1.1 Product identifier**

· Trade name: **HeraCeram Stain Liquid Universal SLU, HeraCeram Pastopaque Liquid POL**

· **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**

Acute Tox. 4 H302 Harmful if swallowed.

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**

H302 Harmful if swallowed.

H336 May cause drowsiness or dizziness.

· **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.



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

· **3.2 Mixtures**

· **Dangerous components:**

CAS: 110-63-4	butane-1,4-diol	Acute Tox. 4, H302; STOT SE 3, H336	>90%
EINECS: 203-786-5			

**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.

Seek medical treatment.

· **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**

Carbon monoxide (CO)

Carbon dioxide (CO<sub>2</sub>)

· **5.3 Advice for firefighters**

· **Protective equipment:**

Do not inhale explosion gases or combustion gases.

Wear self-contained breathing apparatus.

· **Additional information -**

**SECTION 6: Accidental release measures**

· **6.1 Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.

Ensure adequate ventilation

Do not breathe vapor / mist / gas.

· **6.2 Environmental precautions:** Do not allow product to reach sewage system or water bodies.

· **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.

Send for recovery or disposal in suitable containers.

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- **6.4 Reference to other sections**  
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**  
Wear protective equipment. Keep unprotected persons away.  
Avoid contact with eyes and skin.  
Ensure good ventilation/exhaustion at the workplace.  
Do not breathe vapor / mist / gas.
  - **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:**  
Dry place, storage temperature <25 ° C
    - **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:** filter: ABEK
    - **Hand protection**  
Synthetic gloves  
Plastic gloves  
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.

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- **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**

- |   |                                   |
|---|-----------------------------------|
| · <b>Physical state</b>   | Fluid                             |
| · <b>Colour:</b>  | Colourless                        |
| · <b>Smell:</b>   | Odourless                         |
| · <b>Odour threshold:</b>   | Not determined.                   |
| · <b>Melting point/freezing point:</b>                            | 20 °C                             |
| · <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>   | 112 °C (110-63-4 butane-1,4-diol) |
| · <b>Ignition temperature:</b>                                    | 370 °C (110-63-4 butane-1,4-diol) |
| · <b>Decomposition temperature:</b>                               | Not determined.                   |
| · <b>SADT</b>   |                                   |
| · <b>pH at 20 °C</b>  | 7-8                               |
| · <b>Viscosity:</b>   |                                   |
| · <b>Kinematic viscosity</b>                                      | Not determined.                   |
| · <b>dynamic:</b>   | Not determined.                   |
| · <b>Solubility</b>   |                                   |
| · <b>Water:</b>   | Fully miscible                    |
| · <b>Partition coefficient n-octanol/water (log value)</b>        | Not determined.                   |
| · <b>Steam pressure:</b>  | Not determined.                   |
| · <b>Density and/or relative density</b>                          |                                   |
| · <b>Density at 20 °C</b>   | 1.02 g/cm <sup>3</sup>            |
| · <b>Relative density</b>   | Not determined.                   |
| · <b>Vapour density</b>   | Not determined.                   |

· **9.2 Other information**

No further relevant information available.

- |  |  |
|--|--|
| · <b>Appearance:</b>   |  |
| · <b>Form:</b>   | Fluid  |
| · <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.<br>Not determined. |
| · <b>Solvent content:</b>  |  |
| · <b>Solids content:</b>   | 0 %  |

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- **Change in condition**
- **Evaporation rate** Not determined.
- **Information with regard to physical hazard classes**
- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void
- **Flammable solids** Void
- **Self-reactive substances and mixtures** Void
- **Pyrophoric liquids** Void
- **Pyrophoric solids** Void
- **Self-heating substances and mixtures** Void
- **Substances and mixtures, which emit flammable gases in contact with water** Void
- **Oxidising liquids** Void
- **Oxidising solids** Void
- **Organic peroxides** Void
- **Corrosive to metals** Void
- **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:** Strong oxidant, acid chloride, acid anhydride, reductant
- **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**  
Harmful if swallowed.

· **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** No data available.
- **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.

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- **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**  
For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
  - **Additional ecological information:**
    - **General notes:** Avoid transfer into the environment.

**SECTION 13: Disposal considerations**

- **13.1 Waste treatment methods**
  - **Recommendation**  
Disposal must be made according to official regulations.  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
  - **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**

- |   |      |
|---|------|
| · <b>14.1 UN number or ID number</b> <ul style="list-style-type: none"><li>· <b>ADR, ADN, IMDG, IATA</b></li></ul>                            | Void |
| · <b>14.2 UN proper shipping name</b> <ul style="list-style-type: none"><li>· <b>ADR, ADN, IMDG, IATA</b></li></ul>                           | Void |
| · <b>14.3 Transport hazard class(es)</b> <ul style="list-style-type: none"><li>· <b>ADR, ADN, IMDG, IATA</b></li><li>· <b>Class</b></li></ul> | Void |

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- |   |                 |
|---|-----------------|
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>               | Void            |
| · <b>14.5 Environmental hazards:</b><br>· <b>Marine pollutant:</b>    | 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.
- **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:**  
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)  
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)  
ICAO: International Civil Aviation Organisation  
ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)  
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.**