



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

Printing date 28.07.2022

Version number 3 (replaces version 1)

Revision: 28.07.2022

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

· **1.1 Product identifier**

· Trade name: **HeraCeram, HeraCeramSun, HeraCeram Zirkonia**

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*Dentine, Incisal, Transpa, Increaser, Enhancer, Mask, Margin, Gingiva, Correction, Secondary Dentine, Mamelon Dentine, Value, Opal Incisal, Opal Transpa*

· **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 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**

· **3.1 Substances**

· **CAS No. Designation:**

*66402-68-4 ceramic*

· **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.*

(Contd. on page 2)



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- (Contd. of page 1)
- **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.  
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### **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.

(Contd. on page 3)



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(Contd. of page 2)

- **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. 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** Not applicable.
  - **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>
    - **Relative density** Not determined.
    - **Settled apparent density at 20 °C** 830 kg/m<sup>3</sup>

(Contd. on page 4)

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(Contd. of page 3)

· Vapour density	Not applicable.
· Particle characteristics	See item 3.
· 9.2 Other information	No further relevant information available.
· Appearance:	
· Form:	Powder
· 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:	
· Solids content:	100.0 %
· Change in condition	
· Evaporation rate	Not applicable.
· 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.

(Contd. on page 5)



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(Contd. of page 4)

- **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.

· **European waste catalogue**

18 01 07 | chemicals other than those mentioned in 18 01 06

· **Uncleaned packagings:**

- **Recommendation:** Packaging can be reused or recycled after cleaning.

**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

(Contd. on page 6)



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(Contd. of page 5)

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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**

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **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.

· **Date of previous version:** 24.05.2022

· **Version number of previous version:** 1

· **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.**