



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

Printing date 18.10.2021

Version number 3

Revision: 18.10.2021

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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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 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 Chemical characterisation: Substances**

· **Identification number(s):** -

· **3.2 Chemical characterisation: 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.

· **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**
CO₂, 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:** 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**
 - **Additional information about design of technical systems:** No further data; see item 7.
 - **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**
 - **Personal protective equipment**
 - **General protective and hygienic measures**
The usual precautionary measures should be adhered to in handling the chemicals.
 - **Breathing equipment:** Filter P1.
 - **Protection of hands:**
Check protective gloves prior to each use for their proper condition.

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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.
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- **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 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**

· **Appearance:**

- **Form:** Powder
- **Colour:** According to product specification
- **Smell:** Odourless
- **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

- **Melting point/freezing point:** 900 °C
>750 °C
- **Initial boiling point and boiling range:** Not determined

· **Flash point:** Not applicable

· **Inflammability (solid, gaseous)** Not determined.

· **Decomposition temperature:** Not determined.

· **Self-inflammability:** Not determined.

· **Explosive properties:** Product is not explosive.

· **Critical values for explosion:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Steam pressure:** Not applicable.

· **Density at 20 °C** 2.5 g/cm³

- **Settled apparent density at 20 °C** 830 kg/m³
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.

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· Solubility in / Miscibility with · Water:	<i>Insoluble</i>
· Partition coefficient: n-octanol/water:	<i>Not determined.</i>
· Viscosity: · dynamic: · kinematic:	<i>Not applicable.</i> <i>Not applicable.</i>
· Solvent content:	
· Solids content:	<i>100.0 %</i>
· 9.2 Other information	<i>No further relevant information available.</i>

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 toxicological effects**
 - **Acute toxicity** *Based on available data, the classification criteria are not met.*
 - **Primary irritant effect:**
 - **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.
 - **Additional toxicological information:**
 - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **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.*

SECTION 12: Ecological information

- **12.1 Toxicity**
 - **Aquatic toxicity:** *No further relevant information available.*
- **12.2 Persistence and degradability** *No further relevant information available.*
- **12.3 Bioaccumulative potential** *No further relevant information available.*
- **12.4 Mobility in soil** *No further relevant information available.*
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** *Not applicable.*

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- **vPvB:** Not applicable.
- **12.6 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:** Packaging can be reused or recycled after cleaning.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN-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 Transport in bulk according to Annex II of Marpol and the IBC Code | 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**
 - **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

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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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