



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

Printing date 10.05.2023

Version number 1

Revision: 10.05.2023

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

· **1.1 Product identifier**

· Trade name: **HeraCeram Saphir**

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Dentine, Chromadentine, 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 prosthesis*

· **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**
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:**
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 section 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. 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.
 - **Kinematic viscosity**
 - **dynamic:** Not applicable.
 - **Solubility**
 - **Water:** Insoluble
 - **Partition coefficient n-octanol/water (log value)** Not determined.
 - **Steam pressure:** Not applicable.
 - **Vapour pressure:**
 - **Density and/or relative density**
 - **Density at 20 °C** 2.5 g/cm³

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· Relative density	Not determined.
· Settled apparent density at 20 °C	830 kg/m ³
· Vapour density	Not applicable.
· 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.

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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

- | | |
|---|------|
| · 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 |

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|---|-----------------|
| · 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**
 - **LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (UK ANNEX XIV)**
 - **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.**