



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

Printing date 02.08.2022

Version number 1

Revision: 02.08.2022

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

· **1.1 Product identifier**

· Trade name: **HeraCeram Saphir**

· **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**

*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**

· **3.2 Mixtures**

· **Description:** -

· **Dangerous components:** *Void*

**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** *The product is not skin irritating.*

· **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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**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** Avoid causing dust.
- **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 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.
- **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.

· **DNELs**

**13463-67-7 titanium dioxide**

Inhalative	worker industrial, long term, local	10 mg/m <sup>3</sup> (human)
	worker professional, long term, local	10 mg/m <sup>3</sup> (human)

· **PNECs**

**13463-67-7 titanium dioxide**

freshwater	0.127 mg/l (not defined)
marine water	1 mg/l (not defined)

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sediment, dry weight, freshwater	1,000 mg/Kg (not defined)
sediment, dry weight, marine water	100 mg/Kg (not defined)
soil, dry weight	100 mg/Kg (not defined)

· **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 necessary if room is well-ventilated.

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

· **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**

Fluid

· **Colour:**

According to product specification

· **Smell:**

Odourless

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Not determined

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

207 °C (107-88-0 1,3-Butanediol)

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

109 °C (107-88-0 1,3-Butanediol)

· **Decomposition temperature:**

Not determined.

· **SADT**

· **pH**

Not determined.

· **Viscosity:**

· **Kinematic viscosity**

Not determined.

· **dynamic:**

Not determined.

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<ul style="list-style-type: none"><li>· <b>Solubility</b><ul style="list-style-type: none"><li>· <b>Water:</b> Not miscible or difficult to mix</li></ul></li><li>· <b>Partition coefficient n-octanol/water (log value)</b> Not determined.</li><li>· <b>Steam pressure:</b> Not determined.</li><li>· <b>Density and/or relative density</b><ul style="list-style-type: none"><li>· <b>Density at 20 °C</b> 1.8-2.5 g/cm<sup>3</sup></li><li>· <b>Relative density</b> Not determined.</li><li>· <b>Vapour density</b> Not determined.</li></ul></li></ul>	
<ul style="list-style-type: none"><li>· <b>9.2 Other information</b> No further relevant information available.</li><li>· <b>Appearance:</b><ul style="list-style-type: none"><li>· <b>Form:</b> Pasty</li></ul></li><li>· <b>Important information on protection of health and environment, and on safety.</b><ul style="list-style-type: none"><li>· <b>Self-inflammability:</b> Product is not selfigniting.</li><li>· <b>Explosive properties:</b> Product is not explosive. Not determined.</li></ul></li><li>· <b>Solvent content:</b><ul style="list-style-type: none"><li>· <b>Solids content:</b> 75-83 %</li></ul></li><li>· <b>Change in condition</b><ul style="list-style-type: none"><li>· <b>Evaporation rate</b> Not determined.</li></ul></li></ul>	
<ul style="list-style-type: none"><li>· <b>Information with regard to physical hazard classes</b><ul style="list-style-type: none"><li>· <b>Explosives</b> Void</li><li>· <b>Flammable gases</b> Void</li><li>· <b>Aerosols</b> Void</li><li>· <b>Oxidising gases</b> Void</li><li>· <b>Gases under pressure</b> Void</li><li>· <b>Flammable liquids</b> Void</li><li>· <b>Flammable solids</b> Void</li><li>· <b>Self-reactive substances and mixtures</b> Void</li><li>· <b>Pyrophoric liquids</b> Void</li><li>· <b>Pyrophoric solids</b> Void</li><li>· <b>Self-heating substances and mixtures</b> Void</li><li>· <b>Substances and mixtures, which emit flammable gases in contact with water</b> Void</li><li>· <b>Oxidising liquids</b> Void</li><li>· <b>Oxidising solids</b> Void</li><li>· <b>Organic peroxides</b> Void</li><li>· <b>Corrosive to metals</b> Void</li><li>· <b>Desensitised explosives</b> Void</li></ul></li></ul>	

**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

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· **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:**

**107-88-0 1,3-Butanediol**

Oral LD50 18,610 mg/kg (rat)

**13463-67-7 titanium dioxide**

Oral LD50 >5,000 mg/kg (rat) (OECD 420)

**68187-15-5 Zirconia Praseodymium Yellow Zircon**

Oral LD50 >2,200 mg/kg (rat) (OECD 401)

· **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.

· **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:**

**13463-67-7 titanium dioxide**

EC50/72h (static) >100 mg/l (algae) (OECD 201)

EC50/48h (static) >100 mg/l (daphnia) (OECD 202)

LC50/96h (static) >100 mg/l (fish) (OECD 203)

· **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.

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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:** 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

· **14.5 Environmental hazards:**

· **Marine pollutant:**

No

· **14.6 Special precautions for user**

Not applicable.

· **14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

· **Transport/Additional information:**

-

· **UN "Model Regulation":**

Void

**SECTION 15: Regulatory information**

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **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.

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**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:** 15.12.2020

· **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)*

*DNEL: Derived No-Effect Level (REACH)*

*PNEC: Predicted No-Effect Concentration (REACH)*

*LC50: Lethal concentration, 50 percent*

*LD50: Lethal dose, 50 percent*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

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