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

Printing date 13.07.2022 Version number 3 Revision: 13.07.2022

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

- · 1.1 Product identifier
 - · Trade name: HeraCeram Zirkonia 750

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

- 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 inhalation Supply fresh air; consult doctor in case of symptoms.
 - · After skin contact instantly wash with water and soap and rinse thoroughly.
 - · 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.

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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.

Dispose of contaminated material as waste according to item 13.

6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

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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.

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· 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:

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 trough 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:

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Insoluble

Butyl rubber, BR Nitrile rubber. NBR

- Eve/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: Characteristic Odour threshold: Not determined.

· Melting point/freezing point: 760-840 °C · Boiling point or initial boiling point and

boiling range Not determined Product is not inflammable. · Flammability

Lower and upper explosion limit Lower: Not determined. · Upper: Not determined.

Flash point: Not applicable Decomposition temperature: Not determined.

SADT

pH at 20 °C

Viscosity:

Kinematic viscosity Not applicable. dynamic: Not applicable.

Solubility Water:

· Partition coefficient n-octanol/water (log value) Not determined.

· Steam pressure: Not applicable.

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· Density and/or relative density

Density at 20 °C
 Relative density
 Vapour density
 Not determined.
 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 liquids
Pyrophoric solids
Self-heating substances and mixtures
Void
Void

Substances and mixtures, which emit flammable gases in contact with water Void Oxidising liquids Oxidising solids Void Organic peroxides

· 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.

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- 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: 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:

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

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	
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· 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 IMO instruments	g to 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

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.

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) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.