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

Printing date 18.09.2018 Version number 4 Revision: 18.09.2018

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

· **1.1 Product identifier**

· **Trade name:** **HeraCeram Zirkonia Liner, HeraCeram Zirkonia Zr-Adhesive, HeraCeram Zirkonia 750 Adhesive**

· **-** Intensiv-Liner

· **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**
STOT SE 3 H336 May cause drowsiness or dizziness.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.

· **Hazard pictograms**

GHS07

· **Signal word** Warning

· **Hazard-determining components of labelling:**
butane-1,4-diol

· **Hazard statements**
H336 May cause drowsiness or dizziness.

· **Precautionary statements**

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P271	Use only outdoors or in a well-ventilated area.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312	Call a POISON CENTER/doctor if you feel unwell.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.

· **2.3 Other hazards** -

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** -

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Trade name: **HeraCeram Zirkonia Liner, HeraCeram Zirkonia Zr-Adhesive, HeraCeram Zirkonia 750 Adhesive**

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· **Dangerous components:**

CAS: 110-63-4 EINECS: 203-786-5	butane-1,4-diol	Acute Tox. 4, H302; STOT SE 3, H336	10-25%

· **Additional information** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information**
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
· **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.
Drink copious amounts of water and provide fresh air. Instantly call for doctor.
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.

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.
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** Not required.
· **6.2 Environmental precautions:** No special measures required.
· **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
Dispose of contaminated material as waste according to item 13.
· **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** No special measures required.
· **Information about protection against explosions and fires:** No special measures required.

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· **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

· **Additional information about design of technical systems:** No further data; see item 7.

· **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.
· **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:** Not required.
· **Protection of hands:**
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 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:**
Butyl rubber, BR
Nitrile rubber, NBR
· **Eye protection:** not absolutely neccessary
· **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:**	Pasty
· **Colour:**	Different according to colour
· **Smell:**	Characteristic
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.

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· **Change in condition**	
· **Melting point/freezing point:**	Not determined
· **Initial boiling point and boiling range:**	230 °C
· **Flash point:**	134 °C
· **Inflammability (solid, gaseous)**	Not applicable.
· **Ignition temperature:**	385 °C
· **Decomposition temperature:**	Not determined.
· **Self-inflammability:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive.
· **Critical values for explosion:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Steam pressure:**	Not determined.
· **Density at 20 °C**	1.900 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **Water:**	Not miscible or difficult to mix
· **Partition coefficient: n-octanol/water:**	Not determined.
· **Viscosity:**	
· **dynamic:**	Not determined.
· **kinematic:**	Not determined.
· **Solvent content:**	
· **VOC EU**	g/l
· **Solids content:**	30.0 %
· **9.2 Other information**	No further relevant information available.

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

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.

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· **LD/LC50 values that are relevant for classification:**

110-63-4 butane-1,4-diol		
Oral	LD50	1525 mg/kg (rat)

· **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.
· **CMR effects (carcinogenity, 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**
May cause drowsiness or dizziness.
· **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.
· **Additional ecological information:**
· **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **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.

· **European waste catalogue**	
18 01 06	chemicals consisting of or containing dangerous substances

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number**
· **ADR, ADN, IMDG, IATA** Void

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· **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

· **15.2 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.

· **Relevant phrases**

H302 Harmful if swallowed.
H336 May cause drowsiness or dizziness.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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)
VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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