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

Printing date 03.06.2017 Version number 4 Revision: 03.06.2017

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

- · 1.1 Product identifier
 - · Trade name: HeraCeram Glaze
- · 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



- · Signal word Warning
- Hazard-determining components of labelling:

butane-1,4-diol

· Hazard statements

H336 May cause drowsiness or dizziness.

· Precautionary statements

P261 Ávoid breathing dust/fume/gas/mist/vapours/spray. P271 Use only outdoors or in a well-ventilated area.

P304+P340 IF INHÅLED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P312 Call a POISON CENTER/doctor if you feel unwell.

P405 Store locked up.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

- · 2.3 Other hazards -
 - · Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - · **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

· Description: -

· Dangerous components:

CAS: 110-63-4 buta 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.
- · 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

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9.1 Information on basic physical and General Information	l chemical properties	
· Appearance: · Form: · Colour: · Smell: · Odour threshold:	Pasty Different according to colour Characteristic Not determined.	
· pH-value:	Not determined.	
Change in condition Melting point/Melting range: Boiling point/Boiling range:	Not determined 230 °C	
· Flash point:	134 ℃	
· Inflammability (solid, gaseous)	Not applicable.	
· Ignition temperature:	385 ℃	
· Decomposition temperature:	Not determined.	
· Self-inflammability:	Product is not selfigniting.	
· Danger of explosion:	Product is not explosive.	
Critical values for explosion: Lower: Upper:	Not determined. Not determined.	
· Steam pressure:	Not determined.	
 Density at 20 °C Relative density Vapour density Evaporation rate 	1.900 g/cm ³ Not determined. Not determined. Not determined.	
Solubility in / Miscibility with Water:	Not miscible or difficult to mix	
· Partition coefficient (n-octanol/wat	ter): Not determined.	
· Viscosity: · dynamic: · kinematic:	Not determined. Not determined.	
Solvent content: VOC EU	g/l	
Solids content: 9.2 Other information	30.0 % No further relevant information available.	

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

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- · 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.
 - · 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.

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· 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

· 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, IMĎĞ, 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

Not applicable. Marpol and the IBC Code

· 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

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CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweis (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.