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

Printing date 02.08.2022 Version number 3 Revision: 02.08.2022

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

- · 1.1 Product identifier
 - · Trade name: HeraCeram Stain Liquid Universal SLU, HeraCeram Pastopaque Liquid POL
- 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

Acute Tox. 4 H302 Harmful if swallowed.

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 GB CLP regulation.

Hazard pictograms



GHS07

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

butane-1,4-diol

Hazard statements

H302 Harmful if swallowed.

H336 May cause drowsiness or dizziness.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

- · 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 Mixtures

· Dangerous components:

CAS: 110-63-4 butane-1,4-diol

EINECS: 203-786-5

Acute Tox. 4, H302; STOT SE 3, H336

>90%

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
 - · After inhalation Supply fresh air; consult doctor in case of symptoms.
 - · After skin contact

Instantly wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· 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.

Seek medical treatment.

· 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

Carbon monoxide (CO)

Carbon dioxide (CO2)

- 5.3 Advice for firefighters
- Protective equipment:

Do not inhale explosion gases or combustion gases.

Wear self-contained breathing apparatus.

· Additional information -

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Ensure adequate ventilation

Do not breathe vapor / mist / gas.

- · 6.2 Environmental precautions: Do not allow product to reach sewage system or water bodies.
- · 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.

Send for recovery or disposal in suitable containers.

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· 6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

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SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Wear protective equipment. Keep unprotected persons away.

Avoid contact with eyes and skin.

Ensure good ventilation/exhaustion at the workplace.

Do not breathe vapor / mist / gas.

- 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:

Dry place, storage temperature <25 ° C

- 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.
 - · Individual protection measures, such as personal protective equipment
 - General protective and hygienic measures

Keep away from foodstuffs, beverages and food.

Wash hands during breaks and at the end of the work.

· Breathing equipment: filter: ABEK

· Hand protection

Synthetic gloves

Plastic gloves

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.

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· 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 Safety glasses

· 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
Colour:
Smell:
Fluid
Colourless
Odourless

· Odour threshold: Not determined.

• Melting point/freezing point: 20

Boiling point or initial boiling point and

boiling range 230 °C (110-63-4 butane-1,4-diol)

· Flammability Not applicable.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.

• Flash point: 112 °C (110-63-4 butane-1,4-diol) • Ignition temperature: 370 °C (110-63-4 butane-1,4-diol)

· Decomposition temperature: Not determined.

SADT

· pH at 20 °C 7-8

· Viscosity:

· Kinematic viscosity
· dynamic:

Not determined.

Not determined.

Solubility

· Water: Fully miscible

· Partition coefficient n-octanol/water (log

value)Not determined.Steam pressure:Not determined.

Density and/or relative density

Density at 20 °C
 Relative density
 Vapour density
 Not determined.
 Not determined.

• 9.2 Other information No further relevant information available.

Appearance:

· Form: Fluid

Important information on protection of health and environment, and on safety.

• Self-inflammability:
• Explosive properties:

Product is not selfigniting.

Product is not explosive.

Not determined.

· Solvent content:

· Solids content: 0 %

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Void	
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Void	
	Not determined. Void Void Void Void Void Void Void Voi

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: Strong oxidant, acid chloride, acid anhydride, reductant
- · 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

Harmful if swallowed.

· LD/LC50 values that	ara ralavani	for also	cification
· LD/LC50 values that	are reievani	tor cias	isification:

110-63-4 butane-1,4-diol

Oral LD50 1,500 mg/kg (rat)
Dermal LD50 >2,000 mg/kg (rat)

- · 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 No data available.
- 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.

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· 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.
- 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: Avoid transfer into the environment.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
 - Recommendation

Disposal must be made according to official regulations.

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packagings:
 - · Recommendation:

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

· Recommended cleaning agent: Water, if necessary with cleaning agent.

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

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· 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 accordi IMO instruments	ng 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 mixture

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.

Relevant phrases

H302 Harmful if swallowed.

H336 May cause drowsiness or dizziness.

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations RID: Reglement International Concernant le transport des marchandises dangereuses par chemin de les (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

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)

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.