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

Printing date 02.08.2022

Version number 4 (replaces version 3)

Revision: 02.08.2022

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

- · 1.1 Product identifier
 - Trade name: HeraCeram NP-Primer NICHT Final nur für RMA
- · 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

Eye Irrit. 2 H319 Causes serious eye irritation.

- · 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 statements

H319 Causes serious eye irritation.

Precautionary statements

Wear protective gloves / eye protection.

P337+P313 If eye irritation persists: Get medical advice/attention.

- · 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: CAS: 584-03-2 butane-1,2-diol Eye Irrit. 2, H319 ≥10-≤50% EINECS: 209-527-2 Reg.nr.: 01-2120762066-55-xxxx



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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.

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.

· 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.

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 contact with eyes and skin.

Wear protective clothing.

- **6.2 Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- 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.

SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
 - 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.

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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

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

Avoid contact with the eyes and skin.

- · Breathing equipment: Not necessary if room is well-ventilated.
- · 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 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/face protection Tightly sealed 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:
Odour threshold:
Melting point/freezing point:

Fluid
Orange
Characteristic

Not determined

Not determined

· Boiling point or initial boiling point and

boiling range 192 °C (584-03-2 butane-1,2-diol) • Flammability Not applicable.

Lower and upper explosion limit

Lower:

 Upper:
 13.5 Vol % (584-03-2 butane-1,2-diol)

 Flash point:
 13.5 Vol % (584-03-2 butane-1,2-diol)
 13.5 Vol % (584-03-2 butane-1,2-diol)
 13.5 Vol % (584-03-2 butane-1,2-diol)
 13.5 Vol % (584-03-2 butane-1,2-diol)

 Ignition temperature:
 2.4 Vol % (584-03-2 butane-1,2-diol)
 390 °C (584-03-2 butane-1,2-diol)
 390 °C (584-03-2 butane-1,2-diol)

Decomposition temperature: Not determined.

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·SADT

· pH at 20 °C

Viscosity:

· Kinematic viscosity · dynamic:

Solubility Water:

Partition coefficient n-octanol/water (log

value) · Steam pressure:

· Density and/or relative density

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

1.9 g/cm3

Pasty

Not determined.

Not determined.

Fully miscible

6-7

Not determined.
Not determined.
No further relevant information available.

9.2 Other information

Appearance:

· Form:

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

· Self-inflammability: · Explosive properties:

Change in condition
Evaporation rate

Product is not selfigniting. Product is not explosive.

Not determined.

Not determined.

· Information with regard to physical hazard classes

Void · Explosives · Flammable gases Void Void Aerosols Oxidising gases Gases under pressure Void Void Flammable liquids Void Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void Pyrophoric solids Void Self-heating substances and mixtures Void

Substances and mixtures, which emit flammable gases in contact with water

flammable gases in contact with water
Oxidising liquids
Oxidising solids
Organic peroxides
Corrosive to metals
Desensitised explosives
Void
Void
Void
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.

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- · 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.

· LD/LC50 values	that are relevan	t for classification.
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584-03-2 butane-1,2-diol

LD50 >2,000 mg/kg (rat) (OECD 420) Oral Inhalative LC50/4 h 370 mg/l (rat)

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation

Causes serious eve irritation.

- 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:

584-03-2 butane-1,2-diol

EC50/48h | 500 mg/l (daphnia) LC50/96h >10,000 mg/l (fish)

- · 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

The product does not contain substances with endocrine disrupting properties.

- 12.7 Other adverse effects
 - Additional ecological information:
 - General notes: Avoid transfer into the environment.



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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: Disposal must be made according to official regulations.

SECTION 14: Transport information	on	
· 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 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 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

H319 Causes serious eye irritation.

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

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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
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

* Data compared to the previous version altered.