



**Safety Data Sheet  
acc. to OSHA HCS**

Printing date 10/18/2021

Reviewed on 10/18/2021

## 1 Identification

· **Product identifier**

· **Trade name:** HeraCeram Zirkonia Liner

· -

· **Application of the substance / the mixture** Manufacture of dental prothesis

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: [customer.servicehkna@kulzer-dental.com](mailto:customer.servicehkna@kulzer-dental.com)

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

## 2 Hazard(s) identification

· **Classification of the substance or mixture**

Repr. 1B H360 May damage fertility or the unborn child.

STOT SE 3 H336 May cause drowsiness or dizziness.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Danger

· **Hazard-determining components of labeling:**

butane-1,4-diol

N-methyl-2-pyrrolidone

· **Hazard statements**

May damage fertility or the unborn child.

May cause drowsiness or dizziness.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray

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

Call a poison center/doctor if you feel unwell.

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**



Health = 0

Fire = 1

Reactivity = 0

· **HMIS-Ratings (Scale 0-4)**



Health = 0

Fire = 1

Reactivity = 0

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- **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.

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### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
  - **Description:** -

- **Dangerous components:**

110-63-4	butane-1,4-diol Acute Tox. 4, H302; STOT SE 3, H336	≥20-≤50%
872-50-4	N-methyl-2-pyrrolidone Repr. 1B, H360 Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335 Flam. Liq. 4, H227 Specific concentration limit: STOT SE 3; H335: C ≥ 10 %	≥0.1-<1%

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

### 4 First-aid measures

- **Description of first aid measures**
  - **After inhalation** Supply fresh air; consult doctor in case of complaints.
  - **After skin contact** If skin irritation continues, consult a doctor.
  - **After eye contact**  
Rinse opened eye for several minutes under running water. Then consult a doctor.
  - **After swallowing**  
Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.  
Drink copious amounts of water and provide fresh air. Immediately call a doctor.
  - **Information for doctor**
    - **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
    - **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting measures

- **Extinguishing media**
  - **Suitable extinguishing agents**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.
- **Advice for firefighters**
  - **Protective equipment:** No special measures required.
- **Additional information** -

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.

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- **Environmental precautions:**  
No special measures required.  
Prevent seepage into sewage system, workpits and cellars.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).  
Dispose contaminated material as waste according to item 13.
- **Reference to other sections**  
No dangerous substances are released.  
See Section 7 for information on safe handling  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

· **Protective Action Criteria for Chemicals**

· <b>PAC-1:</b>		
110-63-4	butane-1,4-diol	4.7 mg/m <sup>3</sup>
1306-38-3	cerium dioxide	3 mg/m <sup>3</sup>
872-50-4	N-methyl-2-pyrrolidone	30 ppm
7447-41-8	lithium chloride	2.3 mg/m <sup>3</sup>
34590-94-8	Dipropylene glycol monomethyl ether	150 ppm

· <b>PAC-2:</b>		
110-63-4	butane-1,4-diol	52 mg/m <sup>3</sup>
1306-38-3	cerium dioxide	33 mg/m <sup>3</sup>
872-50-4	N-methyl-2-pyrrolidone	32 ppm
7447-41-8	lithium chloride	25 mg/m <sup>3</sup>
34590-94-8	Dipropylene glycol monomethyl ether	1700* ppm

· <b>PAC-3:</b>		
110-63-4	butane-1,4-diol	640 mg/m <sup>3</sup>
1306-38-3	cerium dioxide	200 mg/m <sup>3</sup>
872-50-4	N-methyl-2-pyrrolidone	190 ppm
7447-41-8	lithium chloride	150 mg/m <sup>3</sup>
34590-94-8	Dipropylene glycol monomethyl ether	9900** ppm

**7 Handling and storage**

- **Handling**
  - **Precautions for safe handling**  
No special measures required.  
Ensure good ventilation/exhaustion at the workplace.
  - **Information about protection against explosions and fires:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
  - **Storage**
    - **Requirements to be met by storerooms and receptacles:** No special requirements.
    - **Information about storage in one common storage facility:** Not required.
    - **Further information about storage conditions:** None.

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· **Specific end use(s)** No further relevant information available.

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**8 Exposure controls/personal protection**

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

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the remaining constituent has no known exposure limits.

**872-50-4 N-methyl-2-pyrrolidone**

TLV	BEI
WEEL	Long-term value: 10 ppm Skin

· **Ingredients with biological limit values:**

**872-50-4 N-methyl-2-pyrrolidone**

BEI	100 mg/L Medium: urine Time: end of shift Parameter: 5-Hydroxy-N-methyl-2-pyrrolidone
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· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.

· **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 through 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:** Safety glasses

· **Body protection:** Light weight protective clothing

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**9 Physical and chemical properties**

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:** Fluid  
· **Color:** White  
Pink  
Brown  
Blue

· **Odor:** Characteristic  
· **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· **Melting point/Melting range:** undetermined  
· **Boiling point/Boiling range:** 230 °C (446 °F)

· **Flash point:** 112 °C (233.6 °F)

· **Flammability (solid, gaseous)** Not applicable.

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.  
Not determined.

· **Explosion limits:**

· **Lower:** Not determined.  
· **Upper:** Not determined.

· **Vapor pressure:** Not determined.

· **Density at 20 °C (68 °F):** >0.91631-<1.145 g/cm<sup>3</sup> (>7.64661-<9.55503 lbs/gal)

· **Relative density** Not determined.  
· **Vapor 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:**

· **Solids content:** 24.3-<27.3 %

· **Other information** No further relevant information available.

**10 Stability and reactivity**

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.

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- **Hazardous decomposition products:** none
- **Additional information:** -

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**11 Toxicological information**

- **Information on toxicological effects**

- **Acute toxicity:**

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

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

Oral LD50 1,500 mg/kg (rat)

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

**81-13-0 Dexpantenol**

Oral LD50 15,000 mg/kg (rat)

**872-50-4 N-methyl-2-pyrrolidone**

Oral LD50 3,600 mg/kg (rat)

Dermal LD50 8,000 mg/kg (rabbit)

- **Sensitization:** No sensitizing effects known.

- **Additional toxicological information:** Harmful

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **Reproductive toxicity** Based on available data, the classification criteria are not met.

**12 Ecological information**

- **Toxicity**

- **Aquatic toxicity:** No further relevant information available.

- **Persistence and degradability** No further relevant information available.

- **Behavior in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.

- **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 course or sewage system.

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **Other adverse effects** No further relevant information available.

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**13 Disposal considerations**

- **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.  
Non contaminated packagings can be used for recycling.

**14 Transport information**

· <b>UN-Number</b>	Void
· <b>DOT, ADR, IMDG, IATA</b>	Void
· <b>UN proper shipping name</b>	Void
· <b>DOT, ADR, IMDG, IATA</b>	Void
· <b>Transport hazard class(es)</b>	Void
· <b>DOT, ADR, ADN, IMDG, IATA</b>	Void
· <b>Class</b>	Void
· <b>Packing group</b>	Void
· <b>DOT, ADR, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b>	No
· <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	-
· <b>UN "Model Regulation":</b>	Void

**15 Regulatory information**

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.

· **Sara**

· <b>SARA Section 355 (extremely hazardous substances)</b>
None of the ingredients is listed.

· <b>SARA Section 313 (specific toxic chemical listings)</b>
872-50-4   N-methyl-2-pyrrolidone

· <b>Hazardous Air Pollutants</b>
None of the ingredients is listed.

· **Proposition 65**

· <b>Prop 65 - Chemicals known to cause cancer</b>
None of the ingredients is listed.

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· <b>Chemicals known to cause reproductive toxicity for females:</b>
None of the ingredients is listed.
· <b>Chemicals known to cause reproductive toxicity for males:</b>
None of the ingredients is listed.
· <b>Chemicals known to cause developmental toxicity:</b>
872-50-4   N-methyl-2-pyrrolidone
· <b>Carcinogenicity categories</b>
· <b>EPA (Environmental Protection Agency)</b>
1306-38-3   cerium dioxide   II
· <b>TLV (Threshold Limit Value)</b>
None of the ingredients is listed.
· <b>NIOSH-Ca (National Institute for Occupational Safety and Health)</b>
None of the ingredients is listed.
· <b>Chemical safety assessment: A Chemical Safety Assessment has not been carried out.</b>

**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**

- H227 Combustible liquid.
- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H336 May cause drowsiness or dizziness.
- H360 May damage fertility or the unborn child.

· **Date of preparation / last revision 10/18/2021 / 1**

· **Abbreviations and acronyms:**

- 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
- DOT: US Department of Transportation
- IATA: International Air Transport Association
- 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)
- NFPA: National Fire Protection Association (USA)
- HMIS: Hazardous Materials Identification System (USA)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- NIOSH: National Institute for Occupational Safety
- OSHA: Occupational Safety & Health
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit
- BEL: Biological Exposure Limit
- Flam. Liq. 4: Flammable liquids – Category 4
- Acute Tox. 4: Acute toxicity – Category 4
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
- Repr. 1B: Reproductive toxicity – Category 1B
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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