



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

Printing date 18.10.2021

Version number 5

Revision: 18.10.2021

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

· **1.1 Product identifier**

· Trade name: **HeraCeram Pasteopaque, HeraCeramSun Pasteopaque**

· - Pre-Opaque, Basic-Opaque, Intensive-Opaque, Mono-Opaque

· **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.

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

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

· **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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· Dangerous components:

CAS: 110-63-4 EINECS: 203-786-5	butane-1,4-diol Acute Tox. 4, H302; STOT SE 3, H336	≥20-≤25%
CAS: 872-50-4 EINECS: 212-828-1	N-methyl-2-pyrrolidone Repr. 1B, H360D Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 Specific concentration limit: STOT SE 3; H335: C ≥ 10 %	<0.3%

· SVHC

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

· 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

- **After inhalation** Supply fresh air; consult doctor in case of symptoms.
- **After skin contact** 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.
Drink copious amounts of water and provide fresh air. Instantly call for 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.

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.

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

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See Section 13 for information on disposal.

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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

- **8.1 Control parameters**
 - **Additional information about design of technical systems:** No further data; see item 7.
 - **Components with critical values that require monitoring at the workplace:**

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

OEL (Ireland)	Short-term value: 80 mg/m ³ , 20 ppm Long-term value: 40 mg/m ³ , 10 ppm Sk, IOELV
IOELV (European Union)	Short-term value: 80 mg/m ³ , 20 ppm Long-term value: 40 mg/m ³ , 10 ppm Skin

· **DNELs**

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

Oral	ge.pop., l.te, syst.	0.85 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	4.8 mg/Kg/d (nd)
	ge.pop., l.te, syst.	2.4 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	14.4 mg/m ³ (nd)
	worker industr., l.te., local	40 mg/m ³ (nd)
	ge.pop., l.te, local	4.5 mg/m ³ (nd)

· **PNECs**

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

freshwater	0.25 mg/l (nd)
marine water	0.025 mg/l (nd)
STP	10 mg/l (nd)
sedim., dw, fre.wat.	1.09 mg/Kg (nd)
sedim., dw, mar.wat.	0.109 mg/Kg (nd)
soil,dw	0.07 mg/Kg (nd)

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

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- **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

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Colour:** White
Pink
Brown
Blue

- **Smell:** Characteristic
- **Odour threshold:** Not determined.

- **pH-value:** Not determined.

· **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.
Not determined.

· **Critical values for explosion:**

- **Lower:** Not determined.
- **Upper:** Not determined.

- **Steam pressure:** Not determined.

- **Density at 20 °C** 1.9 g/cm³
- **Relative density** Not determined.

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· 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
 - Additional information: -

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

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

Oral	LD50	3,600 mg/kg (rat)
Dermal	LD50	8,000 mg/kg (rabbit)

- 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.
- Additional toxicological information:
 - CMR effects (carcinogenicity, 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.

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- **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**
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.
- **European waste catalogue**

18 01 06*	chemicals consisting of or containing hazardous substances
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- **Uncleaned packagings:**
 - **Recommendation:**
Disposal must be made according to official regulations.
Non contaminated packagings can be used for recycling.

SECTION 14: Transport information

- | | |
|---|------|
| · 14.1 UN-Number <ul style="list-style-type: none">· ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name <ul style="list-style-type: none">· ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) <ul style="list-style-type: none">· ADR, ADN, IMDG, IATA· Class | Void |
| · 14.4 Packing group <ul style="list-style-type: none">· ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: <ul style="list-style-type: none">· Marine pollutant: | No |

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· **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

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

No further relevant information available.

· **Directive 2012/18/EU**

· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 71, 72

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

no information available

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

no information available

· **Other regulations, limitations and prohibitive regulations**

· **Substances of very high concern (SVHC) according to REACH, Article 57**

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

· **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.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

H360D May damage the unborn child.

· **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

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)

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DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Repr. 1B: Reproductive toxicity – Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
*** Data compared to the previous version altered.**

IE