



**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 10/18/2021

Reviewed on 10/18/2021

1 Identification

· **Product identifier**

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

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

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

· **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.servicehka@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 identification

· **Classification of the substance or mixture**

Reproductive Toxicity - Category 1B

H360 May damage fertility or the unborn child.

Specific Target Organ Toxicity - Single Exposure - Category 3

H336 May cause drowsiness or dizziness.

Category 3

· **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/vapours/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

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· **HMIS-Ratings (Scale 0-4)**

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HEALTH	1	Health = 1
FIRE	1	Fire = 1
REACTIVITY	0	Reactivity = 0

· **Other hazards -**

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Description: -**

· **Dangerous components:**

110-63-4	butane-1,4-diol Acute Toxicity (Oral) - Category 4, H302; Specific Target Organ Toxicity - Single Exposure - Category 3, H336	≥20-≤25% w/w *
872-50-4	N-methyl-2-pyrrolidone Reproductive Toxicity - Category 1B, H360 Skin Irritation - Category 2, H315; Eye Irritation - Category 2A, H319; Specific Target Organ Toxicity - Single Exposure - Category 3, H335 Flammable Liquids - Category 4, H227 Specific concentration limit: Specific Target Organ Toxicity - Single Exposure - Category 3; H335: C ≥ 10 %	≥0.1-<0.5% w/w *

* Actual concentration ranges are withheld as a trade secret.

· **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**

CO₂, 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** No further relevant information available.

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- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information -**

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6 Accidental release measures

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

7 Handling and storage

- **Handling**
 - **Precautions for safe handling** No special measures required.
 - **Information about protection against explosions and fires:** No special measures required.
- **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.
- **Specific end use(s)** No further relevant information available.

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:**

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

EV | TWA: 400 mg/m³

· **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures**
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

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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

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

- **Form:** Pasty
- **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:** 134 °C (273.2 °F)

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

- **Ignition temperature:** 385 °C (725 °F)

- **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):** 1.9 g/cm³ (15.8555 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.

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· Viscosity:	
· dynamic:	Not determined.
· kinematic:	Not determined.
· Solvent content:	
· Solids content:	30.0 %
· 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.
- **Hazardous decomposition products:** none
- **Additional information:** -

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)
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:**

- **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.

- **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.

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- **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.

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

- | | |
|---|-----------------|
| · UN-Number <ul style="list-style-type: none">· DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name <ul style="list-style-type: none">· DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) <ul style="list-style-type: none">· DOT, ADR, ADN, IMDG, IATA· Class | Void |
| · Packing group <ul style="list-style-type: none">· DOT/TDG, ADR, IMDG, IATA | Void |
| · Environmental hazards: <ul style="list-style-type: none">· Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

15 Regulatory information

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

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· Sara

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· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **Chemical safety assessment: A Chemical Safety Assessment has not been carried out.**

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 the latest revision of the safety data sheet 10/18/2021 / 4**

· **Abbreviations and acronyms:**

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

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