



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

Printing date 18.10.2021

Version number 3

Revision: 18.10.2021

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

· **1.1 Product identifier**

· Trade name: **HeraCeram Press Adhesive, HeraCeram Sun Press Adhesive**

· **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:** -

· **Dangerous components:**

CAS: 110-63-4

butane-1,4-diol

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

≥25-≤50%

EINECS: 203-786-5

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· **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**

Formation of toxic gases is possible during heating or in case of fire.

· **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.

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.

Ensure good ventilation/exhaustion at the workplace.

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- **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **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:**
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**
 - **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:** 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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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

- **Form:** Fluid
- **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:** 112 °C

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

· **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** Not determined

· **Relative density** Not determined.

· **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:

· **Water:** 1.4 %

· **Solids content:** 85.5-87.5 %

· 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

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- **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)

81-13-0 Dexpanthenol

Oral	LD50	15,000 mg/kg (rat)
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- **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.
 - **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.

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· **12.6 Other adverse effects** No further relevant information available.

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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.

· **European waste catalogue**

18 01 06* | chemicals consisting of or containing hazardous substances

· **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**

· **ADR, IMDG, IATA**

Void

· **14.2 UN proper shipping name**

· **ADR, 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 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**

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

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· **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

· **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:**

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.**