



# SAFETY DATA SHEET

page 1/6  
CERAMAGE  
SEP

Printing date: April 1, 2020

## SECTION 1. Identification of the substance/mixture and of the company/undertaking

- 1.1 Product identifier  
Trade Name:  
**CERAMAGE "SEP"**
- 1.2 Relevant identified uses of the substance or mixture and uses advised against  
Relevant identified uses: Dental material  
Uses advised against: No further data
- 1.3 Details of the supplier of the safety data sheet  
Company/Undertaking identification  
Manufacturer's Name: SHOFU DENTAL GmbH  
Address: An der Pönt 70, 40885 Ratingen, Germany  
Phone: +49 (0) 2102-8664-0  
Fax: +49 (0) 2102-8664-64  
E-Mail: info@shofu.de  
Section in Charge: Quality Management & Regulatory Affairs
- 1.4 Emergency Telephone Number  
+49-2102-8664-53 (SHOFU DENTAL GmbH) 24 hours / 7 days

## SECTION 2. Hazards identification

- 2.1 Classification of the substance or mixture  
CLASSIFICATION (EC 1272/2008)
- |              |      |                                    |
|--------------|------|------------------------------------|
| Flam.liq. 2  | H225 | Highly flammable liquid and vapour |
| Eye Irrit. 2 | H319 | Causes serious eye irritation      |

- 2.2 Label elements  
LABEL IN ACCORDANCE WITH (EC) NO.1272/2008



GHS02



GHS07

### HAZARD-DETERMINING COMPONENTS OF LABELLING

Ethanol

### SIGNAL WORD

Danger

### HAZARD STATEMENTS

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.

### PRECAUTIONARY STATEMENTS

P210	Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233	Keep container tightly closed.
P242	Use only non-sparking tools.

(Contd. on page2)



# SAFETY DATA SHEET

(Contd. on page1)

- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P303+P361+P353  
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
- P264 Wash hands thoroughly after handling.
- P305+P351+P338  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P337+P313  
If eye irritation persists: Get medical advice/attention.
- P403+P325  
Store in a well-ventilated place. Keep cool.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulation.

## 2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

## SECTION 3. Composition/information on ingredients

- 3.1 Chemical characterization: Mixtures
- 3.2 Description: Mixture of substances listed below with nonhazardous additions.
- 3.3 Dangerous components:

Cas: 64-17-5	Ethanol	55-60 %
EINECS: 200-578-6	Flam. Liq. 2 H225, Eye Irrit. 2 H319	

- 3.4 Additional information: For the wording of the listed risk phrases refer to section 2.

## SECTION 4. First-aid measures

- 4.1 Description of first aid measures
  - Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present. and easy to do. If eye irritation persists, get medical advice/attention.
  - Skin contact: Wash immediately with soap and plenty of water. If on skin, skin irritation, get medical advice/attention.
  - Ingestion: Rinse mouth. Get medical advice/attention.
  - Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If symptom concerning breath goes out, call a POISON CENTER or 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.

(Contd. on page3)



# SAFETY DATA SHEET

(Contd. on page2)

## SECTION 5. Fire-fighting measures

- 5.1 Extinguishing Media:  
CO<sub>2</sub>, Dry chemical, Foam, Dry sand
- 5.2 Special hazards arising from the substance or mixture:  
Easily flammable liquid in room temp.  
In case of fire, irritation gasses and fumes may emit.
- 5.3 Advice for firefighters:  
Wear fire protective cloth and self-contained breathing apparatus, if necessary.

## SECTION 6. Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures:  
Avoid contact with eyes and skin.
- 6.2 Environmental Precautions:  
Send to approved treatment/disposal company or dispose according to local, state and federal regulations.
- 6.3 Methods and material for containment and cleaning up:  
Wipe up and discard in a suitable container.
- 6.4 Reference to other section:  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## SECTION 7. Handling and storage

- 7.1 Precautions for safe handling:  
Handle in a well ventilated place.  
Keep away from naked flames, sparks and sources of heat. No smoking.
- 7.2 Conditions for safe storage, including any incompatibilities:  
Keep container tightly closed. Store in a cool, dark and fireproof area.  
Separated from strong oxidants.
- 7.3 Specific end use(s):  
No further relevant information available

## SECTION 8. Exposure controls/personal protection

- 8.1 Control parameters:  
Exposure limits:

Component		ACGIH (TLV)	NIOSH REL	OSHA PEL
Ethanol	TWA: 1000 ppm TWA; 1920 mg/m <sup>3</sup> TWA WEL-STEL: 3000 ppm STEL; 5760 mg/m <sup>3</sup> STEL	TWA 1000 ppm	TWA 1000 ppm (1900 mg/m <sup>3</sup> )	TWA 1000 ppm (1900 mg/m <sup>3</sup> )

- 8.2 Exposure controls:  
Respiratory Protection:  
Not required.

(Contd. on page4)



# SAFETY DATA SHEET

page 4/6  
CERAMAGE  
SEP  
Printing date: April 1, 2020

(Contd. on page3)

- Skin Protection:**      **Hand Protection**
- The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
- Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture.
- Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
- **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 goggles**

## SECTION 9. Physical and chemical properties

9.1	Information on basic physical and chemical properties	
	Appearance/Odor/Colour:	Slightly milky white liquid with alcohol odor
	Odour threshold	Not determined.
	pH	Not determined.
	Melting point/freezing point	Not determined.
	Boiling Point:	Not determined.
	Flash point:	15.8 °C (closed)
	Evaporation rate	Not determined.
	Flammability (solid, gas)	Not applicable.
	Upper/lower flammability or explosive limits	Not determined.
	Vapour pressure	Not determined.
	Vapour density	Not determined.
	Relative Density:	0.93 (water=1)
	Solubility: water solubility	Soluble
	Partition coefficient: n-octanol/water	Not determined.
	Auto-ignition temperature	Not determined.
	Decomposition temperature	Not determined.
	Viscosity	Not determined.
	Explosive properties	Not applicable.
	Oxidising properties	Not applicable.

(Contd. on page5)



# SAFETY DATA SHEET

(Contd. on page4)

- 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:  
Stable under normal temperatures and pressures.
- 10.3 Possibility of hazardous reactions:  
No dangerous reactions known.
- 10.4 Condition to Avoid:  
Avoid direct sunlight, excess heat, flame and other source of ignition.
- 10.5 Incompatible materials:  
Strong oxidizing materials.
- 10.6 Hazardous Decomposition Products:  
None under normal conditions of storage and use.

## SECTION 11. Toxicological information

- 11.1 Information on toxicological effects:
- |                 |  |
|-----------------|--|
| Acute toxicity: | Ethanol;                                       |
|                 | Oral            mouse   LD50    3450 mg/kg     |
|                 | Inhalation    rat        LC50    20000 ppm/10H |
- Skin corrosion/irritation: Based on available data, the classification criteria are not met.
- Eye damage/irritation: Eye Irrit. 2; H319 Causes serious eye irritation.
- Sensitization to the respiratory tract:  
Based on available data, the classification criteria are not met.
- Skin sensitization: Based on available data, the classification criteria are not met.
- Germ cell mutagenicity/Genotoxicity:  
Based on available data, the classification criteria are not met.
- Carcinogenicity: Ethyl alcohol:  
ACGIH-A4; Not classifiable as a human carcinogen.  
[DFG 2004] MAK; Carcinogen category: 5
- Reproductive toxicity: Based on available data, the classification criteria are not met.
- Effects on or via lactation: Lack of data.
- Specific target organ toxicity (single exposure):  
Based on available data, the classification criteria are not met.
- Specific target organ toxicity (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:  
No further relevant information available.
- 12.2 Persistence and degradability:  
No further relevant information available.

(Contd. on page6)



# SAFETY DATA SHEET

page 6/6  
CERAMAGE  
SEP  
Printing date: April 1, 2020

(Contd. on page5)

- 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:  
Not applicable.
- 12.6 Other adverse effects:  
No further relevant information available.

## SECTION 13. Disposal considerations

- 13.1 Waste treatment methods:  
Dispose of contents/container to in accordance with local/regional/national/international regulations.

## SECTION 14. Transport information

- 14.1 UN number: 1170
- 14.2 UN proper shipping name: ETHANOL, solution
- 14.3 Transport hazard class(es): 3 Flammable liquids.
- 14.4 Packing group: II
- 14.5 Environmental hazards: No further relevant information available.
- 14.6 Special precautions for user: Warning: Flammable liquids.
- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:  
Not applicable.

## SECTION 15. Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:
- EU REGULATIONS: See Section 2
  - Other regulations, limitations and prohibitive regulations:  
The product is a medical device according to the EC-directive 93/42/EEC.
- 15.2 Chemical safety assessment:  
A Chemical Safety Assessment has not been carried out.

## SECTION 16. Other information

This product is intended for use by dental professionals. (instrument/material)

Relevant phrases:

- H225 Highly flammable liquid and vapour.  
H319 Causes serious eye irritation.

Abbreviations and acronyms:

- EINECS: European Inventory of Existing Commercial 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