



SAFETY DATA SHEET

SECTION 1. Identification of the substance or mixture and of the supplier

- 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 INC.**
Address: 11 Kamitakamatsu-cho, Fukuine, Higashiyama-ku, Kyoto 605-0983, JAPAN
Phone: +81-75-561-1112
Fax: +81-75-275-4795
Section in Charge: Quality Assurance Section
- 1.4 Emergency Telephone Number
+81-75-561-1112

SECTION 2. Hazards identification

- 2.1 GHS Classification
- PHYSICAL HAZARDS
- | | |
|--------------------------------------|----------------|
| FLAMMABLE LIQUIDS | Category 2 |
| PYROPHORIC LIQUIDS | Not Classified |
| SELF-HEATING SUBSTANCES AND MIXTURES | Not Classified |
| CORROSIVE TO METALS | Not Classified |
- HEALTH HAZARDS
- | | |
|---|---|
| ACUTE TOXICITY-ORAL | Not Classified |
| ACUTE TOXICITY-INHALATION(VAPOURS, DUST,MIST) | Not Classified |
| SKIN CORROSION/IRRITATION | Not Classified |
| EYE DAMAGE/IRRITATION | Category 2A |
| GERM CELL MUTAGENICITY | Category 1A |
| CARCINOGENICITY | Not Classified |
| TOXIC TO REPRODUCTION | Category 1A |
| SPECIFIC TARGET ORGAN SYSTEMIC TOXICITY (SINGLE EXPOSURE) | Category 3 (respiratory tract irritation, narcotic effects) |
| SPECIFIC TARGET ORGAN SYSTEMIC TOXICITY (REPEATED EXPOSURE) | Category 1 (liver)
Category 2 (nerve) |
- ENVIRONMENTAL HAZARDS
- | | |
|---|----------------|
| HAZARDOUS TO THE AQUATIC ENVIRONMENT-ACUTE HAZARD | Category 3 |
| HAZARDOUS TO THE AQUATIC ENVIRONMENT-CHRONIC HAZARD | Not Classified |
- The thing without mention is out of a classification object. Or cannot classify it.

2.2 Label elements

SYMBOL



GHS02 GHS07 GHS08

HAZARD-DETERMINING COMPONENTS OF LABELLING

Ethanol

SIGNAL WORD Danger

HAZARD STATEMENTS

Highly flammable liquid and vapor.

Causes serious eye irritation.

May cause respiratory irritation.

May cause drowsiness and dizziness.

May cause genetic defects.

May damage fertility or the unborn child.

Causes damage to organs through prolonged or repeated exposure. (liver)

May cause damage to organs through prolonged or repeated exposure. (nerve)

PRECAUTIONARY STATEMENTS

[Prevention]

Do not handle until all safety precautions have been read and understood.

Wear protective gloves and eye/face protection.

Do not breathe dust/fume/gas/mist/vapours/spray.

Do not eat, drink or smoke when using this product.

Keep away from ignition sources such as heat/sparks/open flames-No smoking.

Use only outdoors or in a well-ventilated area.

Keep container tightly closed.

Wash hands thoroughly after handling.

Avoid release to the environment.

[Response]

If in eyes, rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do.

If eye irritation persists, get medical advice/attention.

If on skin, wash with plenty of soap and water. If on skin, skin irritation, get medical advice/attention.

If inhaled, 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.

If swallowed, rinse mouth. Get medical advice/attention.

[Storage]

Store container tightly closed in cool/well-ventilated place.

[Disposal]

Dispose of contents and container in accordance with regulation.



SAFETY DATA SHEET

page 3/7
CERAMAGE
SEP

Printing date: July 20, 2017

- 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:
- Ethanol [Cas.No. 64-17-5] 55-60 %
 - Others
- 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 and seek medical advice if necessary.
 - 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.

SECTION 5. Fire-fighting measures

- 5.1 Extinguishing Media:
- Foam, CO₂, Powder
- 5.2 Special hazards arising from the substance or mixture:
- Easily flammable liquid in room temp.
 - Fire may produce irritating, corrosive and/or toxic gases.
- 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 stable container.
- 6.4 Reference to other section:
- See Section 7 for information on safe handling.



SAFETY DATA SHEET

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:
Store in a cool and dark area with container tightly closed.
- 7.3 Specific end use(s):
No further relevant information available.

SECTION 8. Exposure controls/personal protection

- 8.1 Control parameters:
Exposure limits:
Ethanol [Cas No.64-17-5]:
[ACGIH 2007] 1000 ppm as TWA
NIOSH REL: TWA 1000 ppm (1900 mg/m³)
OSHA PEL: TWA 1000 ppm (1900 mg/m³)
[DFG 2004] MAK: 500 ppm, 960 mg/m³; Peak limitation category: II (2)
OES() Long-term value: 1920 mg/m³, 1000 ppm
- 8.2 Exposure controls:
Respiratory Protection: Not required (use protective gas mask for organic gas, if necessary)
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



SAFETY DATA SHEET

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:	≈ 80 °C
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.

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:

Excessive heat (high temperature), open flames, ignition source, and exposure to sunlight.

10.5 Incompatible materials:

Strong oxidants, Polyvinyl chloride, Acrylic resin, Polystyrene, etc.

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;			
	Inhalation toxicity; mouse	LC50	39 g/m ³ /4H	
		rat	LC50	20000 ppm/10H
	Oral toxicity; mouse	LD50	7500 mg/kg	
		rat	LD50	7060 mg/kg
		rabbit	LD50	6300 mg/kg



SAFETY DATA SHEET

	human	TDL0	0.5 g/kg
	human	LDL0	1400 mg/kg
	rabbit	LDL0	20 g/kg
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.		
Eye damage/irritation:	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:	Ethanol; ACGIH-A4; Not classifiable as a human carcinogen. [DFG 2004] MAK; Carcinogen category: 5		
Reproductive toxicity:	H340 May cause genetic defects. H360 May damage fertility or the unborn child.		
Effects on or via lactation:	Lack of data.		
Specific target organ toxicity (single exposure):	H335 May cause respiratory irritation. H336 May cause drowsiness or dizziness.		
Specific target organ toxicity (repeated exposure):	H372 Causes damage to organs through prolonged or repeated exposure. (liver) H373 May cause damage to organs through prolonged or repeated exposure. (nerve)		
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.
- 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.



SAFETY DATA SHEET

page 7/7
CERAMAGE
SEP

Printing date: July 20, 2017

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: | Not applicable. |
| 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: | Not applicable. |

SECTION 15. Regulatory informati

Follow all regulations in your country.

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.
- H335 May cause respiratory irritation.
- H336 May cause drowsiness and dizziness.
- H340 May cause genetic defects.
- H360 May damage fertility or the unborn child.
- H372 Causes damage to organs through prolonged or repeated exposure. (liver)
- H373 May cause damage to organs through prolonged or repeated exposure. (nerve)

Abbreviations and acronyms:

- 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