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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 date 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

HEALTH HAZARDS

EYE DAMAGE/IRRITATION

Category 2A

The thing without mention is out of a classification object. Or cannot classify it.

2.2 Label elements

SYMBOL





GHS02 GHS07

SIGNAL WORD Danger

HAZARD STATEMENTS

Highly flammable liquid and vapor

Causes serious eye irritation

PRECAUTIONARY STATEMENTS

[Prevention]

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

Wear protective gloves and eye/face protection.

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

Wash hands thoroughly after handling.

[Response]

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.



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 $\label{eq:interpolation} \textbf{IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if}$

present and easy to do. Continue rinsing.

If eye irritation persists, get medical advice/attention.

[Storage]

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

[Disposal]

Dispose of contents and container in accordance with 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:

Ethanol [Cas.No. 64-17-5]

55-60 %

Other component:

Glycerol [Cas.No. 56-81-5]

Polyethylene glycol [Cas.No. 25322-68-3]

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, Dry sand

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.

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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.

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:

Component	ACGIH	NIOSH REL	OSHA PEL
Ethanol	TWA 1000 ppm	TWA 1000 ppm	TWA 1000 ppm
		(1900 mg/m ³)	(1900 mg/m ³)

8.2 Exposure controls:

Respiratory Protection: Not required (use protective mask, 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.



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· 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: ≈ 80 °C

Flash point:

Evaporation rate

Flammability (solid, gas)

Upper/lower flammability or explosive limits

Vapour pressure

Vapour density

Relative Density:

15.8 °C (closed)

Not determined.

Not determined.

Not determined.

Not determined.

0.93 (water=1)

Solubility: water solubility Soluble

Partition coefficient: n-octanol/water
Auto-ignition temperature
Decomposition temperature
Viscosity
Not determined.
Not determined.
Not determined.
Not determined.
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.



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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

 Glycerin; Oral
 rat
 LD50
 12600 mg/kg

 Dermal
 rabbit
 LD50
 > 10 g/kg

Inhalation rat LC50 $> 570 \text{ mg/m}^3/1\text{H}$

Polyethylene glycol;

Oral rat LD50 30200 mg/kg

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Eye damage/irritation: Eye Irrit. 2A; 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: 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.

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.



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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, solution14.3 Transport hazard class(es): 3 Flammable liquids.

14.4 Packing group:

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)

NFPA ratings for USA (scale 0-4)

Ethanol;



Heaith = 2 Fire = 3 Reactivity = 0

Relevan HMIS-Ratings (Scale 0-4)

Ethanol:

Health Hazard	2
Fire Hazard	3
Reactivity	0

Heaith = 2 Fire = 3 Reactivity = 0

Relevant phrases:

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

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