



# SAFETY DATA SHEET

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

- 1.1 Product identifier  
Trade Name:  
**CERAMAGE "OPAQUE & PREOPAQUE"**
- 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   | Not Classified |
| HEALTH HAZARDS  |                |
| ACUTE TOXICITY-ORAL   | Not Classified |
| ACUTE TOXICITY-DERMAL                                       | Not Classified |
| SKIN CORROSION/IRRITATION                                   | Not Classified |
| EYE DAMAGE/IRRITATION                                       | Category 2A    |
| SENSITIZATION-SKIN  | Category 1     |
| GERM CELL MUTAGENICITY                                      | Not Classified |
| TOXIC TO REPRODUCTION                                       | Not Classified |
| SPECIFIC TARGET ORGAN SYSTEMIC TOXICITY (REPEATED EXPOSURE) | Not Classified |
| ENVIRONMENTAL HAZARDS                                       |                |
| HAZARDOUS TO THE AQUATIC ENVIRONMENT-ACUTE HAZARD           | Not Classified |
| 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



GHS07



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## HAZARD-DETERMINING COMPONENTS OF LABELLING

2-Hydroxy Ethyl Methacrylate

UDMA

SIGNAL WORD Warning

## HAZARD STATEMENTS

May cause allergic skin reaction

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.

Do not breathe dust/vapours.

Wash hands thoroughly after handling.

[Response]

IF ON SKIN: Wash with plenty of soap and water.

If skin irritation occurs: Get medical advice/attention.

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 in a cool and dark area.

[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:

2-Hydroxy Ethyl Methacrylate [Cas No. 868-77-9]	4-7 %
Micro fumed silica (amorphous) [Cas No. 112945-52-5]	5-10 %
UDMA[Cas No.72869-86-4]	25-35 %
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.



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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, CO<sub>2</sub>, Powder

5.2 Special hazards arising from the substance or mixture:

In case of fire, irritation gases 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 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:

Avoid inhalation of grindings and prolonged skin contact with uncured resin.

7.2 Conditions for safe storage, including any incompatibilities:

Store in a cool and dark area. (Keep refrigerated when not in use)

7.3 Specific end use(s):

No further relevant information available.

## SECTION 8. Exposure controls/personal protection

8.1 Control parameters:

Ingredients with limit 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.

8.2 Exposure controls:

Respiratory Protection:

Use dust mask while grinding or finishing.



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Skin Protection:	<b>Hand Protection</b> 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. <ul style="list-style-type: none"><li>· 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.</li><li>· 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.</li><li>· For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable: Butyl rubber, BR Nitrile rubber, NBR</li></ul>
Eye Protection:	<b>Safety goggles</b>

## SECTION 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance/Odor/Colour:	Creamy paste multiple shades yellowish white to yellowish brown with sweet odor from acrylate.
Odour threshold	Not determined.
pH	Not determined.
Melting point/freezing point	Not determined.
Boiling Point:	Not determined.
Flash point:	Not determined.
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:	1.69 (OPAQUE), 1.57 (PREOPAQUE) (water=1)
Solubility: water solubility	Insoluble
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.



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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 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: | 2-Hydroxy Ethyl Methacrylate;   |
|                 | Oral rat LD50 > 4000 mg/kg      |
|                 | Dermal rabbit LD50 > 3000 mg/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: H317 May cause an allergic skin reaction.
- Germ cell mutagenicity/Genotoxicity:  
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.
- 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.



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- 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: Void
- 14.2 UN proper shipping name: Void
- 14.3 Transport hazard class(es): Void
- 14.4 Packing group: Void
- 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:

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Abbreviations and acronyms:

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative