




SAFETY DATA SHEET

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

- 1.1 Product identifier
Trade Name:
CERAMAGE "SPACER"
- 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
HEALTH HAZARDS
SENSITIZATION-SKIN Category 1
- The thing without mention is out of a classification object. Or cannot classify it.
- 2.2 Label elements
SYMBOL
- 
- GHS07
HAZARD-DETERMINING COMPONENTS OF LABELLING
Natural rubber latex
SIGNAL WORD Warning
- HAZARD STATEMENTS
May cause allergic skin reaction
- PRECAUTIONARY STATEMENTS
[Prevention]
Do not handle until all safety precautions have been read and understood.
Use only outdoors or in a well-ventilated area.
Do not breathe dust/fume/gas/mist/vapours/spray.
Wash hands thoroughly after handling.
[Response]
If in eyes, rinse cautiously with water for several minutes.



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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 you feel un-well, 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:

Natural rubber latex (solid content)[Cas No.9006-04-6]	55-65 %
Protein originated in latex	0.5-1 %
Water	35-40 %
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:

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.



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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.
- 7.2 Conditions for safe storage, including any incompatibilities:
Keep container tightly closed.
Store avoid direct sunlight and at room temperature (1–30 °C).
- 7.3 Specific end use(s):
No further relevant information available.

SECTION 8. Exposure controls/personal protection

- 8.1 Control parameters:
Exposure limits Rubber, natural (As a pure protein)
ACGIH TLV-TWA 0.001 mg/m³
- 8.2 Exposure controls:
Respiratory Protection:
Dust mask
- 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.



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· 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: | Milky viscous liquid with unique odor. |
| Odour threshold | Not determined. |
| pH | Not determined. |
| Melting point/freezing point | Not determined. |
| Boiling Point: | ≈ 100 °C |
| 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 (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 oxidizing materials.
- 10.6 Hazardous Decomposition Products:
None under normal conditions of storage and use.



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SECTION 11. Toxicological information

11.1 Information on toxicological effects:

Acute toxicity:	Based on available data, the classification criteria are not met.
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Eye damage/irritation:	Based on available data, the classification criteria are not met.
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.
- 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. |



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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.

Abbreviations and acronyms:

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative