



# SAFETY DATA SHEET

(according to 1907/2006/EC, Article 31)

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OneGloss

Printing date: May 29, 2015

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

### 1.1 Product identifier

Trade Name:

**OneGloss**

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

### 1.3 Application of the substance/the preparation

Dental material

### 1.4 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

### 1.5 Emergency Telephone Number

+49-2102-866410 (SHOFU DENTAL GmbH)

## 2. Hazards identification

Classification of the substance or mixture

CLASSIFICATION (67/548)

Not applicable.

CLASSIFICATION (EC 1272/2008)

Not applicable.

LABEL IN ACCORDANCE WITH (EC) NO.1272/2008

Void

HAZARD-DETERMINING COMPONENTS OF LABELLING

SIGNAL WORD

Void

HAZARD STATEMENTS

Void

PRECAUTIONARY STATEMENTS

Void

OTHER HAZARDS

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

## 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: Void

Working part: Synthetic rubber (Polyvinylsiloxiane)

Abrasive grain (Al<sub>2</sub>O<sub>3</sub>)

Silicon oxide (SiO<sub>2</sub>)

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- Others  
Shank part: Stainless steel or Polyphenylenesulfide
- 3.4 Additional information: For the wording of the listed risk phrases refer to section 2.

## 4. First-aid measures

- 4.1 Description of first aid measures  
Eye contact: Wash immediately plenty of water and seek medical advice, since the grinding dust cause scratched harm to the cornea if contact.  
Skin contact: No special measures required.  
Ingestion: No special measures required.  
Inhalation: Remove from exposure. (if inhaled the dust from grinding)
- 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.

## 5. Fire-fighting measures

- 5.1 Extinguishing Media:  
The product is not flammable.
- 5.2 Special hazards arising from the substance or mixture:  
No further relevant information available.
- 5.3 Advice for firefighters:  
No further relevant information available.

## 6. Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures:  
Don't breathe dust.
- 6.2 Environmental Precautions:  
No special measures required.
- 6.3 Methods and material for containment and cleaning up:  
Pick up and collect 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.

## 7. Handling and storage

- 7.1 Precautions for safe handling:  
Use in accordance with instruction. In case of grinding and polishing, wear dust mask and safety glasses, and using dust respirator and local exhaust.
- 7.2 Conditions for safe storage, including any incompatibilities:  
Store in a dry place. Take measures to avoid mechanical and chemical damage.
- 7.3 Specific end use(s):  
No further relevant information available

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## 8. Exposure controls/personal protection

- 8.1 Control parameters:  
Not further data; see item 7.
- 8.2 Exposure controls:  
Respiratory Protection:  
Dust respirator and/or local exhaust.
- Hand Protection: Not required.
- Eye Protection: Safety goggles (May be required)
- Skin Protection: Not required.

## 9. Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
- Appearance/Odor/Colour: Grayish-white colored silicone rubber bonded polishing stone
- Boiling Point: Not determined.
- Flash point: Not determined.
- Relative Density: Not determined.
- Solubility: water solubility Insoluble
- 9.2 Other information  
No further relevant information available.

## 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:  
No further relevant information available.
- 10.5 Incompatible materials:  
No further relevant information available.
- 10.6 Hazardous Decomposition Products:  
None under normal conditions of storage and use.

## 11. Toxicological information

- 11.1 Information on toxicological effects:  
No further relevant information available.

## 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.

## 13. Disposal considerations

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

## 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.

## 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.

## 16. Other information

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