



SAFETY DATA SHEET

SECTION 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
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 DENTAL GmbH
Address: Am Brüll 17, 40878 Ratingen, Germany
Phone: +49 (0) 2102-8664-0
Fax: +49 (0) 2102-8664-64
E-Mail: info@shofu.de
Section in Charge: Quality Management & Regulatory Affairs
- 1.4 Emergency Telephone Number
+49-2102-8664-53 (SHOFU DENTAL GmbH) 24 hours / 7 days

SECTION 2. Hazards identification

- 2.1 Classification of the substance or mixture
CLASSIFICATION (EC 1272/2008)
Not applicable.
- 2.2 Label elements
LABEL IN ACCORDANCE WITH (EC) NO.1272/2008
Void
HAZARD-DETERMINING COMPONENTS OF LABELLING
SIGNAL WORD
Void
HAZARD STATEMENTS
Void
PRECAUTIONARY STATEMENTS
Void
- 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: Void
Working part: Synthetic rubber (Polyvinylsiloxiane)
Abrasive grain (Al₂O₃)
Silicon oxide (SiO₂)
Others

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Shank part: Stainless steel or Polyphenylenesulfide

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: 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.

SECTION 5. Fire-fighting measures

5.1 Extinguishing Media:

CO₂, Dry chemical, Foam

5.2 Special hazards arising from the substance or mixture:

In the case of fire, irritation gas and fume 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:

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.

SECTION 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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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: Dust respirator and/or local exhaust.
Skin Protection: Hand Protection
Not required.
Eye Protection: Safety goggles

SECTION 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 |
| 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: | Not determined. |
| 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. |
- 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.

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- 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.

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: 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: 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.

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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 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.

SECTION 16. Other information

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

Abbreviations and acronyms:

PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative