



SAFETY DATA SHEET

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Dental Rotary Instruments
Printing date: June 27, 2016

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

- 1.1 Product identifier
Trade Name:
**Ceramiste/Brownie/Greenie/Supergreenie/Composite/composite fine/Hardie/
Softcut (PA,PB)/Acrypoint**
- 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
Abrasive grain (SiC)
Magnesium oxide (MgO)

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- Others
Shank part: Stainless steel
- 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: | Brown, green or black colored 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