



SAFETY DATA SHEET

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Merssage
Fine/Regular
Printing date: June 28, 2016

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

- 1.1 Product identifier
Trade Name:
Merssage Fine/Regular
- 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
- | | |
|--|---------|
| Calcium carbonate [Cas No. 1317-65-3] | 10-30 % |
| Glycerin [Cas No. 56-81-5, EINECS 200-289-5] | 10-30 % |
- 3.4 Additional information: For the wording of the listed risk phrases refer to section 2.

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SECTION 4. First-aid measures

4.1 Description of first aid measures

Eye contact: May cause irritation to eyes. Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention if irritation or symptoms persist.

Skin contact: May cause irritation to skin. Wash off immediately with plenty of soap and water. Remove contaminated clothing. Seek medical attention if irritation or symptoms persist.

Ingestion: May cause irritation to mucous membranes. **DO NOT INDUCE VOMITING.** Seek medical attention if irritation or symptoms persist.

Inhalation: May cause irritation to mucous membranes. Move the exposed person to fresh air.

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:

Use extinguishing media appropriate to the surrounding fire conditions.

5.2 Special hazards arising from the substance or mixture:

Burning produces irritating, toxic and obnoxious fumes.

5.3 Advice for firefighters:

Wear suitable respiratory equipment when necessary.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Ensure adequate ventilation of the working area.

6.2 Environmental Precautions:

Do not allow product to enter drains. Prevent further spillage if safe.

6.3 Methods and material for containment and cleaning up:

Sweep up. Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water.

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 contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing.

7.2 Conditions for safe storage, including any incompatibilities:

Keep in a cool, dry, well ventilated area. Keep containers tightly closed. Store in correctly labelled containers.

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- 7.3 Specific end use(s):
No further relevant information available

SECTION 8. Exposure controls/personal protection

- 8.1 Control parameters:
- | Exposure limits | OSHA PEL | ACGIH TLV |
|-----------------|--|----------------------------|
| Glycerin | 15 mg/m ³ (TWA) total
5 mg/m ³ (TWA) resp | 10 mg/m ³ (TWA) |
- 8.2 Exposure controls:
- Respiratory Protection: Ensure adequate ventilation of the working area.
- Skin Protection: Hand Protection
Chemical resistant gloves (PVC).
- Eye Protection: Safety goggles

SECTION 9. Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
- | | |
|--|---------------------------|
| Appearance/Odor/Colour: | Characteristic paste |
| 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 | Slightly soluble in water |
| 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 conditions.

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- 10.3 Possibility of hazardous reactions:
No dangerous reactions known.
- 10.4 Condition to Avoid:
Avoid exposure to direct sun light on the container.
- 10.5 Hazardous Decomposition Products:
None under normal conditions of storage and use.

SECTION 11. Toxicological information

- 11.1 Information on toxicological effects:
- | | | | | |
|-----------------|----------------------|--------|------|-----------------------------|
| Acute toxicity: | Glycerin; Inhalation | rat | LC50 | > 570 mg/m ³ /1H |
| | | mouse | LD50 | 4090 mg/kg |
| | Oral | rat | LD50 | 12600 mg/kg |
| | | rabbit | LD50 | > 10g/kg |
- Dermal
- 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.

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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 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:

EINESC: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative