



SAFETY DATA SHEET

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Pressage

Printing date: May 14, 2024

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

- 1.1 Product identifier
Trade Name:
Pressage
- 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: An der Pönt 70, 40885 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
Void
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.

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Dangerous components:		
Cas: 151-21-3 EINECS: 205-788-1	Sodium dodecyl Sulphate	0-0.5 %
	Flam. Sol. 2, H228; Acute Tox. 4, H302+H332 Skin Irrit. 2, H315; Eye Dam. 1, H318 STOT SE 3, H335; Aquatic Chronic 3: H412	

Others: Glycerin [Cas No. 56-81-5, EINECS 200-289-5] 10-30 %
Titanium dioxide [Cas No. 13463-67-7, EINECS 236-675-5] 1-10 %

3.3 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: 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. Seek medical attention if irritation or symptoms persist.

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.

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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.

7.3 Specific end use(s):

No further relevant information available.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters:

Exposure limits:

Component		ACGIH (TLV)
Glycerin	TWA: 10 mg/m ³ 8 hr (mist only)	TWA 10 mg/m ³ (Glycerin mist)

8.2 Exposure controls:

Respiratory Protection:

Wear suitable respiratory equipment when necessary.

Skin Protection: Hand Protection

Chemical resistant gloves

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 Soluble

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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.
- 10.3 Possibility of hazardous reactions:
No dangerous reactions known.
- 10.4 Condition to Avoid:
Heat. Moisture.
- 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 hazard classes as defined in Regulation (EC) No 1272/2008:
- | | |
|-----------------|---|
| Acute toxicity: | Glycerin; Oral rat LD50 12600 mg/kg |
| | Titanium dioxide; Oral rat LD50 5000 mg/kg bw |
- 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.
- 11.2 Information on other hazards:
No further relevant information available.

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SECTION 12. Ecological information

12.1 Toxicity:

	Daphnia EC50/48h	Algae IC50/72h	Fish LC50/96h
Glycerine	10000 mg/l	2900 mg/l	5000 mg/l
Titanium dioxide	100 mg/l	61 mg/l	1000 mg/l

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 Endocrine disrupting properties:

This product does not contain any known or suspected endocrine disruptors.

12.7 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 or ID 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 Maritime transport in bulk according to IMO instruments:

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).

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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

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