SAFETY DATA SHEET

Printing date: April 3, 2020

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

1.1 Product identifier

Trade Name:

DirectDia Paste

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 date 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

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

Glycerin [Cas No. 56-81-5, EINECS 200-289-5] 55-60 %

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: Rinse cautiously with water for several minutes. Remove contact lenses, if present. and easy to do. If eye irritation persists, get medical advice/attention.

Skin contact: Wash immediately with soap and plenty of water. If on skin, skin irritation, get medical advice/attention.

Ingestion: Rinse mouth. If you feel un-well, get medical advice/attention.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If symptom concerning breath goes out, call a POISON CENTER or doctor.

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:

Water, CO_2, Dry chemical, Foam, Dry sand

5.2 Special hazards arising from the substance or mixture:

No further relevant information available.

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:

Not required.

6.2 Environmental Precautions:

Send to approved treatment/disposal company or dispose according to local, state and federal regulations.

6.3 Methods and material for containment and cleaning up:

Wipe up and discard 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:

Only adequately trained personal should handle this product. For use in dentistry only.

7.2 Conditions for safe storage, including any incompatibilities:

Keep in the refrigerator.

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:

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:

Dust mask

Skin Protection: Hand Protection

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR

Nitrile rubber, NBR

Eye Protection: Safety goggles

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance/Odor/Colour:	Greenish gray color paste like cream
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.

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Vapour pressure	Not determined.
Vapour density	Not determined.
Relative Density:	≈ 2 (water=1)
Solubility: water solubility	Suspend paste in water but not soluble
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.

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;	Oral	rat	LD50	12600 mg/kg
		Dermal	rabbit	LD50	> 10 g/kg
		Inhalation			
			rat	LC50	> 570 mg/m^3/1H

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.

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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.

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)

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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