



SAFETY DATA SHEET

Printing date: October 10, 2024

SECTION 1. Identification of the substance or mixture and of the supplier

- 1.1 Product identifier
Trade Name:
BeutiLink SA
- 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)
- | | | |
|---------------|------|--|
| Eye Irrit. 2A | H319 | Causes serious eye irritation. |
| Acute Tox. 4 | H332 | Harmful if inhaled. |
| Resp. Sens. 1 | H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |

- 2.2 Label elements
LABEL IN ACCORDANCE WITH (EC) NO.1272/2008



GHS07



GHS08

HAZARD-DETERMINING COMPONENTS OF LABELLING

UDMA

Cumene Hydroperoxide

SIGNAL WORD

Danger

HAZARD STATEMENTS

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

PRECAUTIONARY STATEMENTS

P202 Do not handle until all safety precautions have been read and understood.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

(Contd. on page2)

Version Number 2

Revision date: October 10, 2024



SAFETY DATA SHEET

(Contd. of page1)

- P264 Wash hands thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P301+P312
IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
- P304+P340
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P305+P351+P338
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P337+P313
If eye irritation persists: Get medical advice/attention.
- P342+P311
If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

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.

Paste A:

Component	CAS-No	EINECS	%
Zirconium silicate	—	—	40-60
Bis-GMA	1565-94-2	216-367-7	10-20
Bis(methacryloyloxy)dialkylpropane	—	—	10-20
Bis(methacryloyloxy)alkylalcohol	—	—	1-10
Phosphonate monomer	—	—	1-10
Carboxylic acid monomer	—	—	1-5
SiO ₂	68909-20-6	—	1-5
Silane coupling agent	—	—	1-5

Paste B:

Dangerous components:		
Cas: 72869-86-4 EINECS: 276-957-5	UDMA Skin Sens. 1, H317	20-30 %
Cas: 80-15-9 EINECS: 201-254-7	Cumene Hydroperoxide Org. Perox. E, H242; Acute Tox. 4, H302 Acute Tox. 4, H312; Acute Tox. 3, H331 Skin Corr. 1B, H314; STOT RE 2, H372 Aquatic Chronic 2, H411	0.1-0.9 %

(Contd. on page3)



SAFETY DATA SHEET

(Contd. of page2)

Others:

Component	CAS-No	EINECS	%
Glass powder	65997-18-4	—	40-60
Silane coupling agent	—	—	1-10
Bis(methacryloyloxy)dialkylpropane	—	—	1-10
Bis(methacryloyloxy)alkylalcohol	—	—	1-10
SiO ₂	68909-20-6	—	1-5

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: 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. 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:

Powder, Alcohol-resistant foam, Carbon dioxide, Dry sand

5.2 Special hazards arising from the substance or mixture:

Irritation gases and fumes 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:

Avoid eye and skin contact.

6.2 Environmental Precautions:

Attention should be given not to cause damage to the environment by flowing of spillage to rivers.

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.

(Contd. on page4)



SAFETY DATA SHEET

(Contd. of page3)

SECTION 7. Handling and storage

- 7.1 Precautions for safe handling:
Avoid prolonged skin contact with uncured resin.
Keep away from naked flames, sparks and sources of heat.
- 7.2 Conditions for safe storage, including any incompatibilities:
Store in a cool and dark fire proof area with container tightly closed.
- 7.3 Specific end use(s):
No further relevant information available.

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 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: | Paste colored in pale yellow, brown, etc. |
| Odour threshold: | Not determined. |
| pH: | Not determined. |

(Contd. on page5)



SAFETY DATA SHEET

Printing date: October 10, 2024

(Contd. of page4)

Melting point/freezing point:	Not determined.
Boiling point:	Not determined.
Flash point:	> 180 °C
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:	≈ 1.8 (water=1)
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:

May react when in contact with strong oxidants.

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 direct sunlight and high temperature.

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:

Acute Tox. 4; H332 Harmful if inhaled.

Cumene Hydroperoxide;

Oral	rat	LD50	382 mg/kg
Dermal	rat	LD50	500 mg/kg
Inhalation	rat	LC50	220 ppm/4h

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Eye damage/irritation: Eye Irrit. 2A; H319 Causes serious eye irritation.

Sensitization to the respiratory tract:

Resp. Sens. 1; H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(Contd. on page6)

Version Number 2

Revision date: October 10, 2024



SAFETY DATA SHEET

Printing date: October 10, 2024

(Contd. of page5)

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.

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 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.

(Contd. on page7)

Version Number 2

Revision date: October 10, 2024



SAFETY DATA SHEET

page 7/7
BeutiLink SA

Printing date: October 10, 2024

(Contd. of page6)

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).

Relevant phrases:

- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Abbreviations and acronyms:

- EINECS: 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

Version Number 2

Revision date: October 10, 2024