



SAFETY DATA SHEET

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FL-BOND II

PRIMER

Printing date: April 1, 2020

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

1.1 Product identifier

Trade Name:

FL-BOND II "PRIMER"

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)

| | | |
|--------------|------|------------------------------------|
| Flam.liq. 2 | H225 | Highly flammable liquid and vapour |
| Eye Irrit. 2 | H319 | Causes serious eye irritation |

2.2 Label elements

LABEL IN ACCORDANCE WITH (EC) NO.1272/2008



GHS02



GHS07

HAZARD-DETERMINING COMPONENTS OF LABELLING

Ethanol

SIGNAL WORD

Danger

HAZARD STATEMENTS

| | |
|------|-------------------------------------|
| H225 | Highly flammable liquid and vapour. |
| H319 | Causes serious eye irritation. |

PRECAUTIONARY STATEMENTS

| | |
|------|---|
| P210 | Keep away from heat/sparks/open flames/hot surfaces. - No smoking. |
| P233 | Keep container tightly closed. |
| P242 | Use only non-sparking tools. |

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- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P303+P361+P353
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
- P264 Wash hands thoroughly after handling.
- 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.
- P403+P325
Store in a well-ventilated place. Keep cool.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulation.

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:

| | | |
|-------------------|--------------------------------------|---------|
| Cas: 64-17-5 | Ethanol | 30-35 % |
| EINECS: 200-578-6 | Flam. Liq. 2 H225, Eye Irrit. 2 H319 | |

- 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: 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.

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SECTION 5. Fire-fighting measures

- 5.1 Extinguishing Media:
CO₂, Dry chemical, Foam, Dry sand
- 5.2 Special hazards arising from the substance or mixture:
Easily flammable liquid in room temp.
In case of fire, irritation gasses 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 contact with eyes and skin.
- 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:
Handle in a well ventilated place.
Keep away from naked flames, sparks and sources of heat. No smoking.
- 7.2 Conditions for safe storage, including any incompatibilities:
Keep container tightly closed. Store in a cool, dark and fireproof area.
Separated from strong oxidants.
- 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) | NIOSH REL | OSHA PEL |
|-----------|---|-----------------|--|--|
| Ethanol | TWA: 1000 ppm TWA; 1920 mg/m ³ TWA WEL-STEL: 3000 ppm STEL; 5760 mg/m ³ STEL | TWA 1000 ppm | TWA 1000 ppm (1900 mg/m ³) | TWA 1000 ppm (1900 mg/m ³) |

- 8.2 Exposure controls:
Respiratory Protection:
Not required.

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- 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: | Colorless transparent liquid with alcohol odor |
| | Odour threshold | Not determined. |
| | pH | Not determined. |
| | Melting point/freezing point | Not determined. |
| | Boiling Point: | Not determined. |
| | Flash point: | 23 °C (closed) |
| | 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 (water=1) |
| | Solubility: water solubility | 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. |

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9.2 Other information

No further relevant information available.

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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 direct sunlight, excess heat, flame and other source of ignition.

10.5 Incompatible materials:

Strong oxidizing materials.

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:

Ethanol;

Oral mouse LD50 3450 mg/kg

Inhalation rat LC50 20000 ppm/10H

Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

Eye damage/irritation:

Eye Irrit. 2; H319 Causes serious eye irritation.

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:

Ethyl alcohol:

ACGIH-A4; Not classifiable as a human carcinogen.

[DFG 2004] MAK; Carcinogen category: 5

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.

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- 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: 1170
- 14.2 UN proper shipping name: ETHANOL, solution
- 14.3 Transport hazard class(es): 3 Flammable liquids.
- 14.4 Packing group: II
- 14.5 Environmental hazards: No further relevant information available.
- 14.6 Special precautions for user: Warning: Flammable liquids.
- 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)

Relevant phrases:

- H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.

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