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

1.1 Product identifier

Trade Name:

FL-BOND II "ETCHANT"

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)

Skin Irrit. 2 H315 Causes skin irritation

Eye Irrit. 2 H319 Causes serious eye irritation

2.2 Label elements

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



GHS05

HAZARD-DETERMINING COMPONENTS OF LABELLING

Phosphoric acid

SIGNAL WORD

Danger

HAZARD STATEMENTS

H315 Causes skin irritation.

H319 Causes serious eye irritation.

PRECAUTIONARY STATEMENTS

P260 Do not breathe dust/fume/gas/mist/vapour s/spray.

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face

protection.

P301+P330+P331

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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P303+P361+P353

IF ON SKIN (or hair): Remove/Take off immediately all contaminated

clothing. Rinse skin with water/shower.

P363 Wash contaminated clothing before reuse.

P304+P340

IF INHALED: Remove victim to fresh air and keep at rest in a position

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.

P501 Dispose of contents and container in accordance with 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: 7664-38-2	Phosphoric acid	5-10 %	
EINECS: 231-633-2	Skin Irrir. 2; H315, Eye Irrit. 2; H319	5-10 %	

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.

SECTION 5. Fire-fighting measures

5.1 Extinguishing Media:

This product in not flammable.

Use fire extinguishing methods suitable to surrounding conditions.

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5.2 Special hazards arising from the substance or mixture:

Formation of toxic gases is possible during heating or in case of fire.

5.3 Advice for firefighters:

No special measures required.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Avoid eye and skin contact.

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:

Avoid contact with skin and eyes.

Local dust extraction measures are recommended.

7.2 Conditions for safe storage, including any incompatibilities:

Store under normal dry conditions. Keep containers closed.

Keep out of reach of children.

7.3 Specific end use(s):

No further relevant information available.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters:

Exposure limits:

Component		EU	ACGIH(TLV)
Phosphoric acid	STEL: 2 mg/m ³	TWA: 1 mg/m ³ 8 hr	1 mg/m ³ (TWA)
	TWA: 1 mg/m ³	STEL: 2 mg/m ³ 15 min	3 mg/m ³ (STEL)

8.2 Exposure controls

Respiratory Protection:

Not required.

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.

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· 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: Odorless blue-colored jelly

Odour threshold Not determined.

pH Not determined.

Melting point/freezing point Not determined.

Boiling Point: ≈ 100 °C

Flash point:

Evaporation rate

Flammability (solid, gas)

Upper/lower flammability or explosive limits

Vapour pressure

Vapour density

Relative Density:

Not determined.

Not determined.

Not determined.

Not determined.

Not determined.

Not determined.

Solubility: water solubility Soluble

Partition coefficient: n-octanol/water
Auto-ignition temperature
Decomposition temperature
Viscosity
Not determined.
Not determined.
Not determined.
Not determined.
Not applicable.
Oxidising properties
Not applicable.

9.2 Other information

No further relevant information available.

SECTION 10. Stability and reactivity

10.1 Reactivity:

The product has moderate acidity and reacts with a base intensely.

10.2 Chemical stability:

Stable under normal temperatures and pressures.

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10.3 Possibility of hazardous reactions:

No dangerous reactions known.

10.4 Condition to Avoid:

No further relevant information available.

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 toxicological effects:

Acute toxicity: Phosphoric acid;

Oral rat LD50 1530 mg/kg
Dermal rabbit LD50 2740 mg/kg

Skin corrosion/irritation: Skin Irrit. 2; H315 Causes skin irritation.

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: 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: 1805

14.2 UN proper shipping name: Phosphoric acid, solution14.3 Transport hazard class(es): 8 Corrosive substances

14.4 Packing group:

14.5 Environmental hazards: No further relevant information available.

14.6 Special precautions for user: Warning: Corrosive substances.

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:

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Abbreviations and acronyms:

EINESC: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative