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

1.1 Product identifier

Trade Name:

BeautiBond

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: Am Brüll 17, 40878 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.

Skin Sens. 1 H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

STOT SE 3 H366 May cause drowsiness or dizziness.

2.2 Label elements

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





GHS02

GHS07

HAZARD-DETERMINING COMPONENTS OF LABELLING

Acetone

Bis-GMA

SIGNAL WORD

Danger

HAZARD STATEMENTS

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H336	May cause drowsiness or dizziness.

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PRECAUTIONARY STATEMENTS

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

understood.

P210 Keep away from heat/sparks/open flames/hot surfaces.

- No smoking.

P233 Keep container tightly closed.

P261 Avoid breathing dust/fume/gas/mist/vapour s/spray.

P264 Wash hands thoroughly after handling.

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

protection.

P332+P313

If skin irritation occurs: Get medical advice/attention.

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

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: 67-64-1 EINECS: 200-662-2	Acetone	
	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3	40-50 %
	H336	
Cas: 1565-94-2	Bis-GMA	10.15.0/
EINECS: 216-367-7	Skin Sens. 1 H317 H318	10-15 %

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

5.2 Special hazards arising from the substance or mixture:

Easily flammable liquid in room temp.

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:

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:

Store in a cool and dark area with container tightly closed.

Separated from strong oxidants. (Keep refrigerated when not in use.)

7.3 Specific end use(s):

No further relevant information available

SECTION 8. Exposure controls/personal protection

8.1 Control parameters:

Exposure limits Acetone [Cas No.67-64-1]:

-OSHA Permissible Exposure Limit (PEL): 1000 ppm (TWA)

-ACGIH Threshold Limit Value (TLV): 500 ppm (TWA),

750 ppm (STEL) A4 - not classifiable as a human carcinogen

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

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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: Pale yellow liquid with characteristic odor.

Odour threshold Not determined. Not determined. Ha Melting point/freezing point Not determined. Boiling Point: Not determined. Flash point: -15.0 °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: 0.94 (water=1) 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:

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No further relevant information available.

10.2 Chemical stability:

Stable under recommended storage conditions.

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: Acetone: Inhalation rat LC50 75.8 mg/L

Oral rat LD50 > 5000 mg/kg Dermal rabbit LD50 > 5000 mg/kg

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

Eye damage/irritation: H318 Causes serious eye damage.

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: Skin Sens. 1; H317 May cause an allergic skin reaction.

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):

STOT SE 3; H336May cause drowsiness or dizziness.

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:

Acetone:

Fish toxicity: Fathead minnow; LC50/96H > 100 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.

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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: 1090

14.2 UN proper shipping name: Acetone, solution14.3 Transport hazard class(es): 3 Flammable liquids.

14.4 Packing group:

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.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

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