



SAFETY DATA SHEET

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SHOFU Universal Primer

Printing date: January 7, 2019

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

- 1.1 Product identifier
Trade Name:
SHOFU Universal 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: 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. |
| STOT SE 3 | H336 | 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

SIGNAL WORD

Danger

HAZARD STATEMENTS.

| | |
|------|-------------------------------------|
| H225 | Highly flammable liquid and vapour. |
| H319 | Causes serious eye irritation. |
| H336 | May cause drowsiness or dizziness |

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. |

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- 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.

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 | Acetone | 99.0-99.5 % |
| EINECS: 200-662-2 | Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336 | |

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:

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 contact with eyes and skin.

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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.

7.3 Specific end use(s):

No further relevant information available.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters:

Exposure limits

| | ACGIH | NIOSH | OSHA-Final PELs |
|---------|-----------------------------|--|--|
| Acetone | 500 ppm TWA 750 ppm STEL | 250 ppm TWA (590mg/m ³ TWA) 2500 ppm IDLH | 1000 ppm TWA 2400 mg/m ³ TWA |

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.

· 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.

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- 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 liquid with sweet odor |
| Odour threshold | Not determined. |
| pH | Not determined. |
| Melting point/freezing point | Not determined. |
| Boiling Point: | 57 °C (as Acetone) |
| Flash point: | -18 °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: | 0.8 (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. |
- 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 direct sunlight, excess heat, flame and other source of ignition.
- 10.5 Incompatible materials:
Strong oxidizing materials.

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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 toxicity; rat LC50 75.8 mg/L
Oral toxicity; rat LD50 > 5000 mg/kg
Dermal toxicity; rabbit LD50 > 5000 mg/kg

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: 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; H336 May 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.

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.

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SECTION 14. Transport information

- 14.1 UN number: 1090
14.2 UN proper shipping name: Acetone, 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.
H336 May cause drowsiness or dizziness

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