



SAFETY DATA SHEET

(according to 1907/2006/EC, Article 31)

page 1/6
PORCELAIN PRIMER

Printing date: May 29, 2015

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

1.1 Product identifier

Trade Name:

PORCELAIN PRIMER

1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

1.3 Application of the substance/the preparation

Dental material

1.4 Details of the supplier of the safety data sheet

Company/Undertaking identification

Manufacturer's Name: **SHOFU INC.**

Address: 11 Kamitakamatsu-cho, Fukuine, Higashiyama-ku, Kyoto 605-0983, JAPAN

Phone: +81-75-561-1112

Fax: +81-75-275-4795

Section in Charge: Quality Assurance Section

1.5 Emergency Telephone Number

+49-2102-866410 (SHOFU DENTAL GmbH)

2. Hazards identification

Classification of the substance or mixture

CLASSIFICATION (67/548)

F; R11 Highly flammable

CLASSIFICATION (EC 1272/2008)

Flam.liq. 2 H225 Highly flammable liquid and vapour.

Eye Irrit. 2 H319 Causes serious eye irritation.

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



GHS02



GHS07

HAZARD-DETERMINING COMPONENTS OF LABELLING

Ethyl alcohol

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.

(Contd. on page2)



SAFETY DATA SHEET

(according to 1907/2006/EC, Article 31)

page 2/6
PORCELAIN PRIMER

Printing date: May 29, 2015

(Contd. of page1)

- P233 Keep container tightly closed.
- P242 Use only non-sparking tools.
- 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.

OTHER HAZARDS

Results of PBT and vPvB assessment

- PBT: Not applicable.
- vPvB: Not applicable.

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:
- | | | |
|--|-------------------|--------|
| Ethyl alcohol | Cas: 67-17-5 | ≈ 95 % |
| | EINECS: 200-578-6 | |
| F R11 | | |
| Flam. Liq. 2, H225; Eye Irrit. 2, H319 | | |
- 3.4 Additional information: For the wording of the listed risk phrases refer to section 2.

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 to doctor.

(Contd. on page3)



SAFETY DATA SHEET

(according to 1907/2006/EC, Article 31)

page 3/6
PORCELAIN PRIMER

Printing date: May 29, 2015

(Contd. of page2)

- 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.

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.
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.

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.

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

8. Exposure controls/personal protection

- 8.1 Control parameters:
Exposure limits
Ethyl alcohol [Cas No.64-17-5]:
[ACGIH 2007] 1000 ppm as TWA
NIOSH REL: TWA 1000 ppm (1900 mg/m³)
OSHA PEL: TWA 1000 ppm (1900 mg/m³)

(Contd. on page4)



SAFETY DATA SHEET

(according to 1907/2006/EC, Article 31)

page 4/6
PORCELAIN PRIMER

Printing date: May 29, 2015

(Contd. of page3)

[DFG 2004] MAK: 500 ppm, 960 mg/m³; Peak limitation category: II (2)

Not further data; see item 7.

8.2 Exposure controls:

Respiratory Protection:

Not required (use protective gas mask for organic gas, if necessary.)

Hand Protection: Latex or rubber gloves

Eye Protection: Safety goggles (May be required.)

Skin Protection: Not required.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance/Odor/Colour: Colorless transparent liquid with alcohol odor

Flash point: 16 °C (closed)

Relative Density: 0.8 (water=1)

Solubility: water solubility Soluble

9.2 Other information

No further relevant information available.

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.

11. Toxicological information

11.1 Information on toxicological effects:

Ethyl alcohol

Acute toxicity:

[Emergency Response Guidebook]

Vapors may cause dizziness or suffocation.

Inhalation of high concentration of vapor may cause irritation of the respiratory tract. May cause effects on the central nervous system.

Inhalation toxicity:

mouse LC50 39 g/m³/4H

rat LC50 20000 ppm/10H

(Contd. on page5)

Version Number 2

Revision date: April 30, 2015



SAFETY DATA SHEET

(according to 1907/2006/EC, Article 31)

page 5/6
PORCELAIN PRIMER

Printing date: May 29, 2015

(Contd. of page4)

Oral toxicity:

mouse	LD50	7500 mg/kg
rat	LD50	7060 mg/kg
rabbit	LD50	6300 mg/kg
human	TDL0	0.5 g/kg
human	LDL0	1400 mg/kg

Dermal toxicity:

rabbit	LDL0	20 g/kg
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Irritant properties:

[Emergency Response Guidebook]

Inhalation or contact with material may irritate or burn skin and eyes.

Irritating to the eyes.

Inhalation of high concentration of vapor may cause irritation of the eyes.

Irritant properties to skin:

rabbit	400 mg open; MILD
	20 mg/24H; MODERATE

Irritant properties to eyes:

rabbit	500 mg/24H; MILD
rabbit	100 mg/4S rinse; MODERATE

Allergenic and sensitizing effects:

Not available

Chronic toxicity:

Defats the skin.

May have effects on the upper respiratory tract and central nervous system, resulting in irritation, headache, fatigue and lack of concentration.

Chronic ingestion of ethanol may cause liver cirrhosis.

Carcinogenic effects:

ACGIH-A4; Not classifiable as a human carcinogen.

[DFG 2004] MAK; Carcinogen category: 5

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.

(Contd. on page6)

Version Number 2

Revision date: April 30, 2015



SAFETY DATA SHEET

(according to 1907/2006/EC, Article 31)

page 6/6
PORCELAIN PRIMER

Printing date: May 29, 2015

(Contd. of page5)

13. Disposal considerations

13.1 Waste treatment methods:

Dispose of contents/container to in accordance with local/regional/national/international regulations.

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. |

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.

16. Other information

This product is intended for use by dental professionals. (instrument/material)