

SAFETY DATA SHEETS

This SDS packet was issued with item:

076220495

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

076220438 076220446 076220453 076220461 076220479 076220487 076220503 076220511 076220529 076220537
076220545 076220552 076220560 076220578 076220586 076220594 076353932 076353940 076353957 076353965
076353973 076353981 076353999 076354005 076354013 076354021 076354039 076354047 076354054 079704263
079704266 079704269 079704275 079704278 079704281 079704293 273044901 273044902 273044903



SAFETY DATA SHEET

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

page 1/5
BEAUTIFIL II Enamel

Printing date: May 29, 2015

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

1.1 Product identifier

Trade Name:

BEAUTIFIL II Enamel

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)

Xi;	Irritant
R36/38;	Irritating to eyes and skin.
Xi;	Sensitising
R43;	May cause sensitisation by skin contact.

CLASSIFICATION (EC 1272/2008)

Skin Sens. 1	H317	May cause an allergic skin reaction.
	H318	Causes serious eye damage.

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



GHS07

HAZARD-DETERMINING COMPONENTS OF LABELLING

Bis-GMA

SIGNAL WORD Warning

HAZARD STATEMENTS

H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.

(Contd. on page2)

Version Number 1

Date of issue: April 30, 2015



SAFETY DATA SHEET

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

page 2/5
BEAUTIFIL II Enamel

Printing date: May 29, 2015

(Contd. of page1)

PRECAUTIONARY STATEMENTS

- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P261 Avoid breathing dust/fume/gas/mist/vapour s/spray.
- 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.

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:
- | | | |
|---------|-------------------------|--------|
| Bis-GMA | Cas: 1565-94-2 | ≈ 10 % |
| | EINECS: 216-367-7 | |
| | Xi R36/38, Xi R43 | |
| | Skin Sens. 1 H317, H318 | |
- 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.
- 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

(Contd. on page3)

Version Number 1
Date of issue: April 30, 2015



SAFETY DATA SHEET

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

page 3/5
BEAUTIFIL II Enamel

Printing date: May 29, 2015

(Contd. of page2)

- 5.2 Special hazards arising from the substance or mixture:
In case of fire, do not breathe fumes and gases. (Irritation gases 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:
Avoid inhalation of grindings and prolonged skin contact with uncured resin.
- 7.2 Conditions for safe storage, including any incompatibilities:
Store in a cool and dark area. (Keep refrigerated when not in use)
- 7.3 Specific end use(s):
No further relevant information available

8. Exposure controls/personal protection

- 8.1 Control parameters:
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: | Semitransparent high viscosity paste |
| Boiling Point: | Not determined. |
| Flash point: | Not determined. |
| Relative Density: | 1.9 (water=1) |
| Solubility: water solubility | Insoluble |

(Contd. on page4)

Version Number 1
Date of issue: April 30, 2015



SAFETY DATA SHEET

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

page 4/5
BEAUTIFIL II Enamel

Printing date: May 29, 2015

(Contd. of page3)

9.2 Other information

No further relevant information available.

10. Stability and reactivity

10.1 Reactivity:

Polymerization will occur with heat, light.

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:

Protect from exposure to the light.

Keep away from heat and direct sunlight.

10.5 Incompatible materials:

No further relevant information available.

10.6 Hazardous Decomposition Products:

None under normal conditions of storage and use.

11. Toxicological information

11.1 Information on toxicological effects:

Primary irritant effect;

On the skin: Irritant to skin and mucous membranes.

On the eye: Irritating effect.

Sensitization;

Sensitization possible through skin contact.

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.

13. Disposal considerations

13.1 Waste treatment methods:

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

(Contd. on page5)

Version Number 1

Date of issue: April 30, 2015



SAFETY DATA SHEET

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

page 5/5
BEAUTIFIL II Enamel

Printing date: May 29, 2015

(Contd. of page4)

14. Transport information

- | | |
|-------------------------------------------------------------------------------|--------------------------------------------|
| 14.1 UN number: | Void |
| 14.2 UN proper shipping name: | Void |
| 14.3 Transport hazard class(es): | Void |
| 14.4 Packing group: | Void |
| 14.5 Environmental hazards: | No further relevant information available. |
| 14.6 Special precautions for user: | Not applicable. |
| 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)

Version Number 1
Date of issue: April 30, 2015