

page 1/6 BEAUTIFIL II Gingiva

Printing date: April 25, 2024

SECTION 1. Identification of the substance or mixture and of the supplier

1.1 Product identifier

Trade Name:

BEAUTIFIL II Gingiva

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 CORPORATION** Address: 1225 Stone Drive, San Marcos, CA 92078 USA

Toll Free: 1-800-827-4638 Phone: 760-736-3277 Fax: 760-736-3276

E-Mail: customer-service@shofu.com

Section in Charge: Quality Management & Regulatory Affairs

1.4 Emergency Telephone Number

For emergencies only. Call CHEMTREC: +1 703-741-5970 / 1-800-424-9300 (24 hours)

SECTION 2. Hazards identification

2.1 GHS Classification

Not a hazardous substance or mixture according to the Globally Harmonized System (GHS).

2.2 Label elements

SYMBOL Void SIGNAL WORD Void

HAZARD STATEMENTS

Void

PRECAUTIONARY STATEMENTS

[Prevention]

Do not handle until all safety precautions have been read and understood.

[Response]

Get medical advice/attention if you feel unwell.

[Storage]

Store in a cool and dark area.

[Disposal]

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.



page 2/6 BEAUTIFIL II Gingiva

Printing date: April 25, 2024

SECTION 3. Composition/information on ingredients

3.1 Chemical characterization: Mixtures

3.2 Ingredients and composition:

| Component | CAS-No | Weight % |
|----------------------------------|-------------|----------|
| Aluminofluoro-borosilicate glass | 65997-18-4 | 60-70 |
| Bis-GMA | 1565-94-2 | 10-15 |
| TEGDMA | 109-16-0 | 1-10 |
| Silane coupling agent | _ | 1-10 |
| UDA | _ | 1-10 |
| AI_2O_3 | 1344-28-1 | 1-5 |
| SiO ₂ | 100402-78-6 | 1-5 |
| Pigments | _ | |
| Others | _ | |

3.3 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, Dry sand

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.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Avoid contact with eyes and skin.

6.2 Environmental Precautions:

Do not allow product to reach sewage system or water bodies.

Do not allow to enter the ground/soil.



page 3/6 BEAUTIFIL II Gingiva

Printing date: April 25, 2024

6.3 Methods and material for containment and cleaning Up:

Wipe up and discard in a stable 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 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.

7.3 Specific end use(s):

No further relevant information available.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters:

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls:

Respiratory Protection:

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

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.

• 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



page 4/6 BEAUTIFIL II Gingiva

Printing date: April 25, 2024

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Appearance/Odor/Colour: Pink high viscosity paste.

Odour threshold: Not determined. pH: Not determined. Melting point/freezing point: Not determined. Boiling point: Not determined. Flash point: Not determined. Not determined. Evaporation rate: Flammability (solid, gas): Not applicable. Upper/lower flammability or explosive limits: Not determined. Vapour pressure: Not determined. Vapour density: Not determined. Relative density: 1.9 (water=1)

Solubility: water solubility
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:

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.

SECTION 11. Toxicological information

11.1 Information on toxicological effects:

Acute toxicity: Based on available data, the classification criteria are not met.

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

Eye damage/irritation: Based on available data, the classification criteria are not met.

Sensitization to the respiratory tract:

Based on available data, the classification criteria are not met.



page 5/6 BEAUTIFIL II Gingiva

Printing date: April 25, 2024

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.

11.2 Information on other hazards:

No further relevant information available.

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.

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: 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.

SECTION 15. Regulatory information

Follow all regulations in your country.

Version Number 4 Revision date: April 25, 2024



page 6/6 BEAUTIFIL II Gingiva

Printing date: April 25, 2024

SECTION 16. Other information

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

Abbreviations and acronyms:

CAS: Chemical Abstracts Service (division of the American Chemical Society)

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

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