

SAFETY DATA SHEET

ESTELITE BULK FILL Flow

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

1.1. Product identifier

Product name ESTELITE BULK FILL Flow

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

Identified uses Resin-based dental restorative material. For dental professionals only.

1.3. Details of the supplier of the safety data sheet

Supplier Tokuyama Dental Italy S.r.l.
Via Chizzalunga, 1,
36066 Sandrigo, Vicenza, Italy
TEL: +39-0444-659650
FAX: +39-0444-750345

Contact person <http://www.tokuyama-dental.com/tdc/contact.html>

Manufacturer Tokuyama Dental Corporation
38-9, Taitou 1-chome, Taitou-ku, Tokyo
110-0016, Japan
TEL: +81-3-3835-2261
FAX: +81-3-3835-2265

1.4. Emergency telephone number

Emergency telephone Regional Medicines and Poisons Information Centre NI,
Pharmacy Department
Royal Hospital Suite, Grosvenor Road, Belfast
Emergency telephone: 844 892 0111
Telephone: +44 28 90 63 2032
Fax: +44 28 90 24 8030
E-mail address: nirdic.nirdic@belfasttrust.hscni.net

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Not Classified

Health hazards Skin Irrit 2 - H315: Eye Irrit 2 - H319: Skin Sens. 1 - H317

Environmental hazards Not Classified

2.2. Label elements

Pictogram



Signal word Warning

Hazard statements H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

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Precautionary statements	<p>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</p> <p>P302+P352 IF ON SKIN: Wash with plenty of water.</p> <p>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P501 Dispose of contents/ container in accordance with local regulations.</p>
Contains	<p>(1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE, 2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE, (1-METHYLETHYLIDENE)BIS(4,1-PHENYLENEOXY-2,1-ETHANEDIYLOXY-2,1-ETHANEDIYL) BISMETHACRYLATE, 2-(2H-BENZOTRIAZOL-2-YL)-p-CRESOL</p>
Supplementary precautionary statements	<p>P261 Avoid breathing vapours.</p> <p>P264 Wash contaminated skin thoroughly after handling.</p> <p>P272 Contaminated work clothing should not be allowed out of the workplace.</p> <p>P321 Specific treatment (see medical advice on this label).</p> <p>P332+P313 If skin irritation occurs: Get medical advice/ attention.</p> <p>P333+P313 If skin irritation or rash occurs: Get medical advice/ attention.</p> <p>P337+P313 If eye irritation persists: Get medical advice/ attention.</p> <p>P362+P364 Take off contaminated clothing and wash it before reuse.</p>

2.3. Other hazards

This product does not contain any substances classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

(1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE 10-30%
CAS number: 1565-94-2 EC number: 216-367-7
Classification Skin Sens. 1 - H317 Aquatic Chronic 3 - H412
2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE 10-30%
CAS number: 109-16-0 EC number: 203-652-6
Classification Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 Skin Sens. 1 - H317
(1-METHYLETHYLIDENE)BIS(4,1-PHENYLENEOXY-2,1-ETHANEDIYLOXY-2,1-ETHANEDIYL) BISMETHACRYLATE 5-10%
CAS number: 41637-38-1 EC number: 609-946-4
Classification Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 Skin Sens. 1 - H317 STOT SE 3 - H335

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2-(2H-BENZOTRIAZOL-2-YL)-p-CRESOL	<1%
CAS number: 2440-22-4	EC number: 219-470-5
Classification Skin Sens. 1 - H317 Aquatic Chronic 3 - H412	
MEQUINOL	<1%
CAS number: 150-76-5	EC number: 205-769-8
Classification Acute Tox. 4 - H302 Eye Irrit. 2 - H319 Skin Sens. 1 - H317	
2,6-DI-tert-BUTYL-p-CRESOL	<1%
CAS number: 128-37-0	EC number: 204-881-4
M factor (Chronic) = 1	
Classification Aquatic Chronic 1 - H410	
TITANIUM DIOXIDE	<1%
CAS number: 13463-67-7	EC number: 236-675-5
Classification Acute Tox.4 - H332 Carc.2 - H351	

The full text for all hazard statements is displayed in Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information	Move affected person to fresh air at once. Get medical attention if any discomfort continues.
Inhalation	Move affected person to fresh air at once.
Ingestion	Try to induce vomiting. Get medical attention if any discomfort continues.
Skin contact	Wash skin thoroughly with soap and water.
Eye contact	Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes. Continue to rinse for at least 15 minutes. Get medical attention if irritation persists after washing.

4.2. Most important symptoms and effects, both acute and delayed

Skin contact	Skin irritation. Allergic rash.
Eye contact	May cause severe eye irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor	No specific recommendations.
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SECTION 5: Firefighting measures

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5.1. Extinguishing media

Suitable extinguishing media Extinguish with the following media: Foam. Carbon dioxide or dry powder.

5.2. Special hazards arising from the substance or mixture

Specific hazards Irritating gases or vapours.

Hazardous combustion products No known hazardous decomposition products.

5.3. Advice for firefighters

Protective actions during firefighting Avoid breathing fire gases or vapours.

Special protective equipment for firefighters Wear chemical protective suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Wear protective clothing as described in Section 8 of this safety data sheet.

6.2. Environmental precautions

Environmental precautions No specific recommendations.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Absorb in vermiculite, dry sand or earth and place into containers. Eliminate all sources of ignition. No smoking, sparks, flames or other sources of ignition near spillage. Provide adequate ventilation.

6.4. Reference to other sections

Reference to other sections For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions All handling should only take place in well-ventilated areas.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store in a cool, dark place (0-25°C, 32-77°F). Keep away from heat, direct sunlight, sparks and open flames.

Storage class Chemical storage.

7.3. Specific end use(s)

Specific end use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Occupational exposure limits

2,6-DI-tert-BUTYL-p-CRESOL

Long-term exposure limit (8-hour TWA): WEL 10 mg/m³

TITANIUM DIOXIDE

Long-term exposure limit (8-hour TWA): WEL 4 mg/m³ respirable dust

Long-term exposure limit (8-hour TWA): WEL 10 mg/m³ inhalable dust

WEL = Workplace Exposure Limit

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8.2. Exposure controls

Appropriate engineering controls	Provide adequate general and local exhaust ventilation.
Eye/face protection	The following protection should be worn: Chemical splash goggles.
Hand protection	Wear protective gloves.
Other skin and body protection	Wear appropriate clothing to prevent any possibility of skin contact.
Hygiene measures	Do not smoke in work area. Wash hands at the end of each work shift and before eating, smoking and using the toilet. Wash promptly with soap and water if skin becomes contaminated. Promptly remove any clothing that becomes contaminated. Use appropriate skin cream to prevent drying of skin. When using do not eat, drink or smoke.
Respiratory protection	No specific recommendations. Respiratory protection must be used if the airborne contamination exceeds the recommended occupational exposure limit.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance	Paste
Colour	Yellow-white, translucent yellow
Odour	Not available.
Odour threshold	Not available.
pH	Not applicable.
Melting point	Not available.
Initial boiling point and range	Not available.
Flash point	Not applicable.
Evaporation rate	Not available.
Evaporation factor	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	Not applicable.
Other flammability	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	1.65
Solubility(ies)	Not available.
Partition coefficient	Not available.
Auto-ignition temperature	Not available.
Decomposition Temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.

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Oxidising properties Not available.

9.2. Other information

Other information Not available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity There are no known reactivity hazards associated with this product.

10.2. Chemical stability

Stability Stable at normal ambient temperatures and when used as recommended.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions Not known.

10.4. Conditions to avoid

Conditions to avoid Keep away from heat, sparks and open flame. Protect against direct sunlight.

10.5. Incompatible materials

Materials to avoid Strong oxidising agents.

10.6. Hazardous decomposition products

Hazardous decomposition products Heating may generate the following products: Toxic gases or vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Route of entry See section 4.2.

Acute toxicity - oral

Notes (oral LD₅₀) Not available.

Acute toxicity - dermal

Notes (dermal LD₅₀) Not available.

Acute toxicity - inhalation

Notes (inhalation LC₅₀) Not available.

Skin corrosion/irritation

Skin corrosion/irritation Causes skin irritation.

Animal data

Not available.

Serious eye damage/irritation

Serious eye damage/irritation Causes serious eye irritation.

Respiratory sensitisation

Respiratory sensitisation Not available.

Skin sensitisation

Skin sensitisation May cause an allergic skin reaction.

Germ cell mutagenicity

Genotoxicity - in vitro Not available.

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Genotoxicity - in vivo	Not available.
<u>Carcinogenicity</u>	
Carcinogenicity	Not available. Not established : IARC, NTP, EU, OSHA, ACGIH
<u>Reproductive toxicity</u>	
Reproductive toxicity - fertility	Not available.
Reproductive toxicity - development	Not available.
<u>Specific target organ toxicity - single exposure</u>	
STOT - single exposure	Not available.
<u>Specific target organ toxicity - repeated exposure</u>	
STOT - repeated exposure	Not available.
<u>Aspiration hazard</u>	
Aspiration hazard	Not available.

SECTION 12: Ecological Information

12.1. Toxicity

Acute toxicity - fish	Not available.
Acute toxicity - aquatic invertebrates	Not available.
Acute toxicity - aquatic plants	Not available.
Chronic toxicity - fish early life stage	Not available.
Short term toxicity - embryo and sac fry stages	Not available.
Chronic toxicity - aquatic invertebrates	Not available.

12.2. Persistence and degradability

Persistence and degradability	No data available.
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12.3. Bioaccumulative potential

Bioaccumulative potential	No data available on bioaccumulation.
Partition coefficient	Not available.

12.4. Mobility in soil

Mobility	No information available.
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12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment	This product does not contain any substances classified as PBT or vPvB.
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12.6. Other adverse effects

Other adverse effects	Not known.
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SECTION 13: Disposal considerations

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13.1. Waste treatment methods

Disposal methods Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

SECTION 14: Transport information

General The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk according to Not applicable.

**Annex II of MARPOL 73/78
and the IBC Code**

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU legislation (EC) No 1907/2006 (REACH).
(EC) No 1272/2008 (CLP).
(EU) No 2015/830.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Classification procedures according to Regulation (EC) 1272/2008 Skin Irrit. 2 - H315: Calculation method. Skin Sens. 1 - H317: Calculation method. Eye Irrit. 2 - H319: Calculation method.

Training advice There is a specific duty on the importer/user/distributor of the substances and mixtures to ensure that the workers have received appropriate training and refresher training.

Revision comments

Revision date 15/09/2018

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Revision	4
Hazard statements in full	H302 Harmful if swallowed. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H332 Harmful if inhaled. H335 May cause respiratory irritation. H351 Suspected of causing cancer. H410 Very toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects.

The information which is contained in this document is based on available data. However, as such has been obtained from various sources, including independent laboratories, it is given without warranty or representation that is complete, accurate and can be relied upon. Tokuyama Dental Corp. has not attempted to conceal in any way the deleterious aspects of the product listed herein, but makes no warranty as to such information.