

Revision Date 10/11/2014

Revision 1

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 dell'Artigianato, 7, 36030 Montecchio,
Precalcino (VI), Italy
TEL: +39-0445-334545
FAX: +39-0445-339133

Contact Person <http://www.tokuyama-dental.com/contact.htm>

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

Guy's & St Thomas' Poisons Unit
Medical Toxicology Unit
Guy's & St Thomas' Hospital Trust Mary Sheridan House
15 St Thomas Street
London SE1 9RY
TEL: +44 (0)20 7188 0600
FAX: +44 (0)20 7188 0800
<http://www.medtox.org.uk>
<http://www.who.int/ipcs/poisons/centre/en/>

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical and Chemical Hazards	Not classified.
Human health	Skin Irrit. 2 - H315; Eye Irrit. 2 - H319; Skin Sens. 1 - H317
Environment	Not classified.

Classification (1999/45/EEC)

Xi; R36/38. R43.

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

2.2. Label elements

Contains (1-METHYLETHYLIDENE)BIS(4,1-PHENYLENEOXY-2,1-ETHANEDIYLOXY-2,1-ETHANEDIYL)
BISMETHACRYLATE
(1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)]
BISMETHACRYLATE
2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE

Label In Accordance With (EC) No. 1272/2008



ESTELITE BULK FILL Flow

Signal Word	Warning	
Hazard Statements	H315	Causes skin irritation.
	H317	May cause an allergic skin reaction.
	H319	Causes serious eye irritation.
Precautionary Statements	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P302+352	IF ON SKIN: Wash with plenty of soap and water.
	P305+351+338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P501	Dispose of contents/container in accordance with local regulations.
Supplementary Precautionary Statements	P272	Contaminated work clothing should not be allowed out of the workplace.
	P261	Avoid breathing vapour/spray.
	P264	Wash contaminated skin thoroughly after handling.
	P321	Specific treatment (see medical advice on this label).
	P332+313	If skin irritation occurs: Get medical advice/attention.
	P333+313	If skin irritation or rash occurs: Get medical advice/attention.
	P337+313	If eye irritation persists: Get medical advice/attention.
	P362	Take off contaminated clothing and wash before reuse.
	P363	Wash contaminated clothing before reuse.

2.3. Other hazards

This product does not contain any PBT or vPvB substances.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

(1-METHYLETHYLIDENE)BIS(4,1-PHENYLENEOXY-2,1-ETHANEDILOY-2,1-ETHANEDIYL) BISMETHACRYLATE 5-10%										
CAS-No.: 41637-38-1 EC No.: 609-946-4										
<table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Classification (EC 1272/2008)</td> <td style="width: 50%;">Classification (67/548/EEC)</td> </tr> <tr> <td>Skin Irrit. 2 - H315</td> <td>Xi;R36/37/38.</td> </tr> <tr> <td>Eye Irrit. 2 - H319</td> <td>R43.</td> </tr> <tr> <td>Skin Sens. 1 - H317</td> <td></td> </tr> <tr> <td>STOT SE 3 - H335</td> <td></td> </tr> </table>	Classification (EC 1272/2008)	Classification (67/548/EEC)	Skin Irrit. 2 - H315	Xi;R36/37/38.	Eye Irrit. 2 - H319	R43.	Skin Sens. 1 - H317		STOT SE 3 - H335	
Classification (EC 1272/2008)	Classification (67/548/EEC)									
Skin Irrit. 2 - H315	Xi;R36/37/38.									
Eye Irrit. 2 - H319	R43.									
Skin Sens. 1 - H317										
STOT SE 3 - H335										
(1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE 10-30%										
CAS-No.: 1565-94-2 EC No.: 216-367-7										
<table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Classification (EC 1272/2008)</td> <td style="width: 50%;">Classification (67/548/EEC)</td> </tr> <tr> <td>Skin Sens. 1 - H317</td> <td>R43,R53.</td> </tr> <tr> <td>Aquatic Chronic 3 - H412</td> <td></td> </tr> </table>	Classification (EC 1272/2008)	Classification (67/548/EEC)	Skin Sens. 1 - H317	R43,R53.	Aquatic Chronic 3 - H412					
Classification (EC 1272/2008)	Classification (67/548/EEC)									
Skin Sens. 1 - H317	R43,R53.									
Aquatic Chronic 3 - H412										
2-(2H-BENZOTRIAZOL-2-YL)-p-CRESOL < 1%										
CAS-No.: 2440-22-4 EC No.: 219-470-5										
<table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Classification (EC 1272/2008)</td> <td style="width: 50%;">Classification (67/548/EEC)</td> </tr> <tr> <td>Skin Sens. 1 - H317</td> <td>R43,R53.</td> </tr> <tr> <td>Aquatic Chronic 4 - H413</td> <td></td> </tr> </table>	Classification (EC 1272/2008)	Classification (67/548/EEC)	Skin Sens. 1 - H317	R43,R53.	Aquatic Chronic 4 - H413					
Classification (EC 1272/2008)	Classification (67/548/EEC)									
Skin Sens. 1 - H317	R43,R53.									
Aquatic Chronic 4 - H413										

ESTELITE BULK FILL Flow

2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE		10-30%
CAS-No.: 109-16-0	EC No.: 203-652-6	
Classification (EC 1272/2008) Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 Skin Sens. 1 - H317	Classification (67/548/EEC) Xi;R36/38. R43.	
DL-BORNANE-2,3-DIONE		< 1%
CAS-No.: 10373-78-1	EC No.: 233-814-1	
Classification (EC 1272/2008) Not classified.	Classification (67/548/EEC) Not classified.	

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General information

Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.

Inhalation

Move the exposed person to fresh air at once.

Ingestion

Try to induce vomiting. Get medical attention if any discomfort continues.

Skin contact

Wash the skin immediately with soap and water.

Eye contact

Make sure to remove any contact lenses from the eyes before rinsing. Promptly wash eyes with plenty of water while lifting the eye lids. Continue to rinse for at least 15 minutes. Contact physician if irritation persists.

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

Skin contact

Skin irritation. Allergic rash.

Eye contact

May cause severe irritation to eyes.

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

No specific recommendations.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing media

Fire can be extinguished using: Foam. Carbon dioxide or dry powder.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products

No hazardous decomposition products.

Specific hazards

When heated and in case of fire, irritating vapours/gases may be formed.

5.3. Advice for firefighters

ESTELITE BULK FILL Flow

Special Fire Fighting Procedures

Avoid breathing fire vapours.

Protective equipment for fire-fighters

Wear full protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

No specific recommendations.

6.3. Methods and material for containment and cleaning up

Absorb in vermiculite, dry sand or earth and place into containers. Extinguish all ignition sources. Avoid sparks, flames, heat and smoking. Ventilate.

6.4. Reference to other sections

For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

All handling to take place in well-ventilated area.

7.2. Conditions for safe storage, including any incompatibilities

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)

The identified uses for this product are detailed in Section 1.2.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Name	STD	TWA - 8 Hrs		STEL - 15 Min		Notes
2,6-DI-tert-BUTYL-p-CRESOL	WEL		10 mg/m ³			
TITANIUM DIOXIDE	WEL		10 mg/m ³			

WEL = Workplace Exposure Limit.

8.2. Exposure controls

Protective equipment



Engineering measures

Provide adequate general and local exhaust ventilation.

Respiratory equipment

No specific recommendation made, but respiratory protection must be used if the general level exceeds the recommended occupational exposure limit.

Hand protection

Wear protective gloves.

ESTELITE BULK FILL Flow

Eye protection

Wear approved safety goggles.

Other 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 & 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.

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.
Solubility	Not available.
Initial boiling point and boiling range (°C)	Not available.
Melting point (°C)	Not available.
Relative density	1.65
Vapour density (air=1)	Not available.
Vapour pressure	Not available.
Evaporation rate	Not available.
Evaporation Factor	Not available.
pH-Value, Conc. Solution	Not available.
Viscosity	Not available.
Solubility Value (G/100G H₂O@20°C)	Not available.
Decomposition temperature (°C)	Not available.
Odour Threshold, Lower	Not available.
Odour Threshold, Upper	Not available.
Flash point (°C)	Not available.
Auto Ignition Temperature (°C)	Not available.
Flammability Limit - Lower(%)	Not applicable.
Flammability Limit - Upper(%)	Not applicable.
Partition Coefficient (N-Octanol/Water)	Not available.
Explosive properties	Not available.
Other Flammability	Not available.
Oxidising properties	Not available.

ESTELITE BULK FILL Flow

9.2. Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No specific reactivity hazards associated with this product.

10.2. Chemical stability

Stable under normal temperature conditions and recommended use.

10.3. Possibility of hazardous reactions

Not known.

10.4. 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

Toxic gases are generated when heated.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity:

Acute Toxicity (Oral LD50)

Not available.

Acute Toxicity (Dermal LD50)

Not available.

Acute Toxicity (Inhalation LC50)

Not available.

Skin Corrosion/Irritation:

Not available.

Serious eye damage/irritation:

Not available.

Respiratory or skin sensitisation:

Respiratory sensitisation

Not available.

Skin sensitisation

Not available.

Germ cell mutagenicity:

Genotoxicity - In Vitro

Not available.

Genotoxicity - In Vivo

Not available.

Carcinogenicity:

Carcinogenicity

Not available.

Not established : IARC, NTP, EU, OSHA, ACGIH

ESTELITE BULK FILL Flow

Reproductive Toxicity:

Reproductive Toxicity - Fertility

Not available.

Reproductive Toxicity - Development

Not available.

Specific target organ toxicity - single exposure:

STOT - Single exposure

Not available.

Specific target organ toxicity - repeated exposure:

STOT - Repeated exposure

Not available.

Aspiration hazard:

Viscosity

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.

12.2. Persistence and degradability

Degradability

No data available.

12.3. Bioaccumulative potential

Bioaccumulative potential

No data available on bioaccumulation.

Partition coefficient

Not available.

12.4. Mobility in soil

Mobility:

No information available.

12.5. Results of PBT and vPvB assessment

This product does not contain any PBT or vPvB substances.

12.6. Other adverse effects

Not known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste and residues in accordance with local authority requirements.

SECTION 14: TRANSPORT INFORMATION

General

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

ESTELITE BULK FILL Flow

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 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 Legislation

Dangerous Substance Directive 67/548/EEC.

Dangerous Preparations Directive 1999/45/EC.

(EC) No 1907/2006 (REACH).

(EC) No 1272/2008 (CLP).

(EU) No 453/2010.

15.2. Chemical Safety Assessment

No chemical safety assessment has been carried out.

SECTION 16: OTHER INFORMATION

Revision Comments

This is first issue.

Revision Date 10/11/2014

Revision 1

Risk Phrases In Full

NC Not classified. , R34 Causes burns. , R36/37/38 Irritating to eyes, respiratory system and skin. , R36/38 Irritating to eyes and skin. , R43 May cause sensitisation by skin contact. , R53 May cause long-term adverse effects in the aquatic environment.

Hazard Statements In Full

H315 Causes skin irritation. , H317 May cause an allergic skin reaction. , H319 Causes serious eye irritation. , H335 May cause respiratory irritation. , H412 Harmful to aquatic life with long lasting effects. , H413 May cause long lasting harmful effects to aquatic life.

Disclaimer

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.