

**ESTELITE BULK FILL Flow**

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) &amp; 2020/878

**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 Use(s) **【Medical Device】** Resin-based Dental Restorative Material. For dental professionals only.

Uses Not Recommended Use only for intended applications

**1.3 Details of the supplier of the safety data sheet****Manufacturer**Company Identification Tokuyama Dental Corporation  
Address of Manufacturer 38-9, Taitou 1-chome, Taitou-ku, Tokyo, Japan

Postal code 110-0016

Telephone: +81-3-3835-2261

Fax +81-3-3835-2265

**Supplier**Company Identification Tokuyama Dental Italy S.r.l.  
Address of Supplier Via Chizzalunga, 1, 36066 Sandrigo, Vicenza, Italy

Telephone: +39-0444-659650

Fax +39-0444-750345

**E-mail**

http://www.tokuyama-dental.com/tdc/contact.html

**1.4 Emergency telephone number**

Emergency Phone No. (UK)844 892 0111

Contact 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

**National response center**

Contact NHS Direct

Emergency Phone No. +44 111

**SECTION 2: HAZARDS IDENTIFICATION****2.1 Classification of the substance or mixture**Regulation (EC) No. 1272/2008 (CLP) Skin Irrit 2 - Causes skin irritation.  
Eye Irrit 2 - Causes serious eye irritation.  
Skin Sens 1 -May cause an allergic skin reaction.**2.2 Label elements**Product Name According to Regulation (EC) No. 1272/2008 (CLP)  
ESTELITE BULK FILL Flow**Hazard Pictogram(s)**Signal Word(s) GHS07  
WarningHazard Statement(s) H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.Precautionary Statement(s) P261 Avoid breathing vapours.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
P302+P352 IF ON SKIN: Wash with plenty of water.  
P305+P351+P338 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.**2.3 Other hazards**

**ESTELITE BULK FILL Flow**

This product does not contain any substances classified as PBT or vPvB.  
Endocrine disrupting properties: Not known.

**2.4 Additional Information**

Contains:

(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,

For full text of H/P Statements see section 16.

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS****3.1 Substances**

Not applicable.

**3.2 Mixtures**

| HAZARDOUS INGREDIENT(S)  | CAS No.    | EC No. / REACH Registration No.    | % W/W | Hazard Statement(s)  | Hazard Pictogram(s) |
|--|------------|------------------------------------|-------|--|---------------------|
| COMPOSITE FILLER   | -          | -                                  | 30-50 | Not Classified   | -                   |
| REACTION MASS OF SILICON DIOXIDE AND ZIRCONIUM DIOXIDE                                     | -          | 910-388-1<br>01-2119860534-36-0000 | 20-40 | Not Classified   | -                   |
| (1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE       | 1565-94-2  | 216-367-7                          | 10-30 | Skin Sens. 1 H317<br>Aquatic Chronic 3 H412  | GHS07               |
| 2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE   | 109-16-0   | 203-652-6                          | 10-30 | Skin Irrit. 2 H315<br>Skin Sens. 1 H317<br>Eye Irrit. 2 H319                           | GHS07               |
| (1-METHYLETHYLIDENE)BIS(4,1-PHENYLENEOXY-2,1-ETHANEDIYLOXY-2,1-ETHANEDIYL) BISMETHACRYLATE | 41637-38-1 | 609-946-4                          | 5-10  | Skin Irrit. 2 - H315<br>Eye Irrit. 2 - H319<br>Skin Sens. 1 - H317<br>STOT SE 3 - H335 | GHS07               |
| SILICATE GLASS   | -          | -                                  | <5    | Not Classified   |                     |
| TITANIUM DIOXIDE   | 13463-67-7 | 236-675-5                          | <0.1  | Acute Tox. 4 - H332<br>Carc. 2 - H351  | GHS07<br>GHS08      |
| MEQUINOL   | 150-76-5   | 205-769-8                          | <0.1  | Acute Tox. 4 H302<br>Skin Sens. 1 H317<br>Eye Irrit. 2 H319                            | GHS07               |
| 2,6-DI-tert-BUTYL-p-CRESOL   | 128-37-0   | 204-881-4                          | <0.1  | Aquatic Chronic 1 H410   | GHS09               |

| HAZARDOUS INGREDIENT(S)    | CAS No.  | Specific concentration limits | M-factor,             | ATE                       |
|----------------------------|----------|-------------------------------|-----------------------|---------------------------|
| MEQUINOL                   | 150-76-5 |                               |                       | Acute Tox. 4 (H302) : 500 |
| 2,6-DI-tert-BUTYL-p-CRESOL | 128-37-0 |                               | M factor (Chronic) =1 |                           |

Contains no non-classified vPvB substances.

Contains no non-classified substances with a Union workplace exposure limit.

For full text of H/P Statements see section 16.

**SECTION 4: FIRST AID MEASURES****4.1 Description of first aid measures**

|              |  |
|--------------|--|
| General      | Move affected person to fresh air at once. Get medical attention if any discomfort continues   |
| Inhalation   | Move affected person to fresh air at once. Get medical attention if any discomfort continues   |
| Skin Contact | Wash with plenty of soap and water. Take off contaminated clothing and wash it before reuse.   |
| 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. |
| Ingestion    | Try to induce vomiting. Get medical attention if any discomfort continues.   |

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

|              |                                 |
|--------------|---------------------------------|
| Skin contact | Skin irritation. Allergic rash. |
| Eye contact  | Causes serious eye irritation.  |

**ESTELITE BULK FILL Flow****4.3 Indication of any immediate medical attention and special treatment needed**

No specific recommendations.

**SECTION 5: FIREFIGHTING MEASURES****5.1 Extinguishing media**

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

Unsuitable extinguishing media Not known.

**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**

Do not allow to enter drains, sewers or watercourses. This material and its container must be disposed of in a safe way.

**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**

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 temperature (°C) 0-25°C .

Storage life Stable under normal conditions.

Incompatible materials Incompatible with organic peroxides. Oxidizing agents, Acids, Alkalis .

**7.3 Specific end use(s)**

【Medical Device】 Resin-based Dental Restorative Material. For dental professionals only.

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1 Control parameters****8.1.1 Occupational Exposure Limits**

| Occupational Exposure Limits          |            |                        |                                       |               |                              |       |
|---------------------------------------|------------|------------------------|---------------------------------------|---------------|------------------------------|-------|
| SUBSTANCE.                            | CAS No.    | LTEL<br>(8 hr TWA ppm) | LTEL<br>(8 hr TWA mg/m <sup>3</sup> ) | STEL<br>(ppm) | STEL<br>(mg/m <sup>3</sup> ) | Note  |
| TITANIUM DIOXIDE<br>(respirable dust) | 13463-67-7 |                        | 4                                     |               |                              | WEL   |
| TITANIUM DIOXIDE<br>(inhalable dust)  | 13463-67-7 |                        | 10                                    |               |                              | WEL   |
| 2,6-DI-tert-BUTYL-p-CRESOL            | 128-37-0   |                        | 10                                    |               |                              | WEL   |
| 2,6-DI-tert-BUTYL-p-CRESOL            | 128-37-0   |                        | 10                                    |               |                              | Comp, |





|                |   |
|----------------|---|
| Region         | Source  |
| EU             | EU Occupational Exposure Limits   |
| United Kingdom | UK Workplace Exposure Limits EH40/2005 (Fourth edition, published 2020) |
| Remark         | Notes   |
| IOELV          | Indicative Occupational Exposure Limit Values.                          |
| WELL           | Workplace Exposure Limit  |

**ESTELITE BULK FILL Flow****8.2 Exposure controls**

## 8.2.1. Appropriate engineering controls

Provide adequate general and local exhaust ventilation.

## 8.2.2. Personal protection equipment

|   |                        |   |
|---|------------------------|---|
|  | Eye Protection         | The following protection should be worn: Chemical splash goggles. Wear eye protection with side protection (EN166).   |
|  | Skin protection        | Wear protective gloves. Wear appropriate clothing to prevent any possibility of skin contact.: Impervious gloves (EN 374). Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible. Gloves should be changed regularly to avoid permeation problems. Wear solvent-resistant apron and boots. |
|  | Respiratory protection | No specific recommendations. Respiratory protection may be required if excessive airborne contamination occurs.   |
|  | Thermal hazards        | No specific recommendations. Respiratory protection must be used if the airborne contamination exceeds the recommended occupational exposure limit.   |
|   | 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.   |

## 8.2.3. Environmental Exposure Controls

Avoid release to the environment. Keep container tightly sealed when not in use.

**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   | Technical impossibility to obtain the data.                                |
| Melting point/freezing point                 | Not available.   |
| Initial boiling point and boiling range      | Not available.   |
| Flash Point                                  | Not available.   |
| Evaporation rate                             | Not available.   |
| Flammability (solid, gas)                    | Not available.   |
| Upper/lower flammability or explosive limits | Not available.   |
| Vapour pressure                              | Not available.   |
| Vapour density                               | Not available.   |
| Density (g/ml)                               | Not available.   |
| Relative density                             | 1.7  |
| Solubility(ies)                              | Solubility (Water) : Not available.<br>Solubility (Other) : Not available. |
| Partition coefficient: n-octanol/water       | Not available.   |
| Auto-ignition temperature                    | Not available.   |
| Decomposition Temperature (°C)               | Not available.   |
| Viscosity                                    | Not available.   |
| Explosive properties                         | Not available.   |
| Oxidising properties                         | Not available.   |

**9.2 Other information**

Not available.

**ESTELITE BULK FILL Flow****SECTION 10: STABILITY AND REACTIVITY****10.1 Reactivity**

May polymerise. See the other subsections of this section for further details.

**10.2 Chemical Stability**

Stable at normal ambient temperatures and when used as recommended

**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**

Combustion or thermal decomposition may evolve toxic vapours.  
Toxic gases/vapours (Carbon monoxide, Carbon dioxide)

**SECTION 11: TOXICOLOGICAL INFORMATION****11.1 Information on toxicological effects**

Acute toxicity - Ingestion

Not classified.

Acute toxicity - Skin Contact

Not classified.

Acute toxicity - Inhalation

Not classified.

Skin corrosion/irritation

Calculation method : Skin Irrit 2 - Causes skin irritation.

Serious eye damage/irritation

Calculation method : Eye Irrit 2 - Causes serious eye irritation.

Skin sensitization data

Calculation method : Skin Sens 1 -May cause an allergic skin reaction.

Respiratory sensitization data

Not classified.

Germ cell mutagenicity

Not classified.

Carcinogenicity

Not classified.

TITANIUM DIOXIDE(CAS No. 13463-67-7)Acute toxicity - inhalation

ATE inhalation(dusts/mists mg/l) 1.5

Carcinogenicity

IARC carcinogenicity : IARC Group 2B Possibly carcinogenic to humans.

NTP carcinogenicity : Reasonably anticipated to be a human carcinogen.

OSHA Carcinogenicity Not listed.

2,6-DI-tert-BUTYL-p-CRESOL (CAS No. 128-37-0)Carcinogenicity

IARC carcinogenicity : IARC Group 3

Not classifiable as to its carcinogenicity to humans.

NTP carcinogenicity : Male : rat-negative, mice-negative

Female : rat-negative, mice-negative

OSHA Carcinogenicity Not listed.

Reproductive toxicity

Not classified.

Lactation

Not classified.

STOT - single exposure

Not classified.

STOT - repeated exposure

Not classified.

Aspiration hazard

Not classified.

**11.2 Other information**

Route(s) of entry

Skin, Eyes, Ingestion, Inhalation, Health effects: See section 4.2.

Endocrine disrupting properties: Not known.

**SECTION 12: ECOLOGICAL INFORMATION****12.1 Toxicity**

Toxicity - Aquatic invertebrates

Not available.

Toxicity - Fish

Not available.

Toxicity - Algae

Not available.

Toxicity - Sediment Compartment

Not available.

Toxicity - Terrestrial Compartment

Not available.

**12.2 Persistence and degradability**

No data available,.

**12.3 Bioaccumulative potential**

**ESTELITE BULK FILL Flow**

Bioaccumulative potentia

No data available on bioaccumulation.

Partition coefficient

Not available.

**12.4 Mobility in soil**

No information available.

**12.5 Results of PBT and vPvB assessment**

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

**12.6 Endocrine disrupting properties**

Endocrine disrupting properties: Not known.

**12.7 Other adverse effects**

Not known.

**SECTION 13: DISPOSAL CONSIDERATIONS****13.1 Waste treatment methods**

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

Must not be disposed of together with household garbage. Dispose at suitable refuse site. Do not allow to enter drains, sewers or watercourses. Empty containers may retain some product residues and hence be potentially hazardous.

**13.2 Additional Information**

Disposal should be in accordance with local, state or national legislation.

**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**

No.

**14.6 Special precautions for user**

Not applicable.

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

**SECTION 15: REGULATORY INFORMATION****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

European Regulations - Authorisations and/or Restrictions On Use

|   |  |
|---|--|
| Candidate List of Substances of Very High Concern for Authorisation   | Not listed   |
| REACH: ANNEX XIV list of substances subject to authorisation  | Not listed   |
| REACH: Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles | Not listed   |
| Community Rolling Action Plan (CoRAP)   | 2,6-DI-tert-BUTYL-p-CRESOL (128-37-0), 2-(2H-BENZOTRIAZOL-2-YL)-p-CRESOL (2440-22-4), (1-METHYLETHYLIDENE)BIS(4,1-PHENYLENEOXY-2,1-ETHANEDIYLOXY-2,1-ETHANEDIYL) BISMETHACRYLATE(41637-38-1) |
| Regulation (EC) N° 850/2004 of the European Parliament and of the Council on persistent organic pollutants                              | Not listed   |
| Regulation (EC) N° 1005/2009 on substances that deplete the ozone layer   | Not listed   |
| Regulation (EU) N° 649/2012 of the European Parliament and of the Council   | Not listed   |

**ESTELITE BULK FILL Flow**

|   |  |
|---|--|
| concerning the export and import of hazardous chemicals |  |
| Directive 93/42/EEC                                     | This product is a medical device as defined in Directive 93/42/EEC (MDD), which is invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). Although not required, the product is classified and labelled according to the CLP regulation. |

**National regulations**

Other

Not known.

**15.2 Chemical Safety Assessment**

A REACH chemical safety assessment has not been carried out.

**SECTION 16: OTHER INFORMATION**

The following sections contain revisions or new statements:

Training advice

Ensure operatives are trained to minimise exposure. Only trained personnel should use this material.

Date of First Issue

30-05-2016

Date of Revision

15-12-2022

Revision ( EU )

5

**LEGEND**

Hazard Pictogram(s)



Hazard classification

GHS07

GHS08: GHS: Health hazard

GHS09: GHS: Environment

Acute Tox. 4 : Acute toxicity, Category 4

Skin Irrit. 2 : Skin corrosion/irritation, Category 2

Skin Sens. 1 : Skin sensitization, Category 1

Eye Irrit. 2 : Serious eye damage/irritation, Category 2

Carc. 2 : Carcinogenicity Category 2

STOT SE 3 : Specific target organ toxicity — single exposure, Category 3

Aquatic Chronic 1 : Hazardous to the aquatic environment, Chronic, Category 1

Aquatic Chronic 3 : Hazardous to the aquatic environment, Chronic, Category 3

Hazard Statement(s)

H302: Harmful if swallowed.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H332 Harmful if inhaled.

H351 Suspected of causing cancer.

H335 May cause respiratory irritation.

H410: Very toxic to aquatic life with long lasting effects.

H412: Harmful to aquatic life with long lasting effects.

Precautionary Statement(s)

P261 Avoid breathing vapours.

P264 Wash contaminated skin thoroughly after handling.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P321 Specific treatment (see medical advice on this label).

P332+P313 If skin irritation occurs: Get medical advice/ attention.

P333+P313 If skin irritation or rash occurs: Get medical advice/ attention.

P337+P313 If eye irritation persists: Get medical advice/ attention.

P362+P364 Take off contaminated clothing and wash it before reuse.

P501 Dispose of contents/ container in accordance with local regulations

Acronyms

ADN : European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

**ESTELITE BULK FILL Flow**

ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road

CAS : Chemical Abstracts Service

CLP : Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

DNEL : Derived No Effect Level

EC : European Community

EINECS : European Inventory of Existing Commercial Chemical Substances

IATA : International Air Transport Association

IBC : Intermediate Bulk Container

ICAO : International Civil Aviation Organization

IMDG : International Maritime Dangerous Goods

LTEL : Long term exposure limit

PBT : Persistent, Bioaccumulative and Toxic

PNEC : Predicted No Effect Concentration

REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals

RID : Regulations concerning the International Carriage of Dangerous Goods by Rail

STEL : Short term exposure limit

STOT : Specific Target Organ Toxicity

UN : United Nations

vPvB : very Persistent and very Bioaccumulative

WEL : Workplace Exposure Limit

**Disclaimers**

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.