

ESTELITE UNIVERSAL FLOW

(Medium, Super Low, High)

Date of Issue :

30-09-2017

Date of Revision:

15-12-2022

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

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product Name ESTELITE UNIVERSAL FLOW (Medium, Super Low, High)

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.

STOT SE 3 - May cause respiratory irritation.

2.2 Label elements

According to Regulation (EC) No. 1272/2008 (CLP)

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Hazard Pictogram(s)



GHS07

Warning

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

Precautionary Statement(s)

P261 Avoid breathing vapour/ spray.

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

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

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

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

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P501 Dispose of contents/ container in accordance with local regulations.

2.3 Other hazards

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-2,1-ETHANEDIYOXY-2,1-ETHANEDIYL) BISMETHACRYLATE,
2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE,
(1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)]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 01-2119860534-36-0000	20-40	Not Classified	-
(1-METHYLETHYLIDENE)BIS(4,1-PHENYLENEOXY-2,1-ETHANEDIYOXY-2,1-ETHANEDIYL) BISMETHACRYLATE	41637-38-1	609-946-4	0-30	Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 Skin Sens. 1 - H317 STOT SE 3 - H335	GHS07
(1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE	1565-94-2	216-367-7	0-20	Skin Sens. 1 H317 Aquatic Chronic 3 H412	GHS07
2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE	109-16-0	203-652-6	5-20	Skin Irrit. 2 H315 Skin Sens. 1 H317 Eye Irrit. 2 H319	GHS07
7,7,9(OR 7,9,9)-TRIMETHYL-4,13-DIOXO-3,14-DIOXA-5,12-DIAZAHEXADECANE-1,16-DIYL BISMETHACRYLATE	72869-86-4	276-957-5	0-5	Skin Sens. 1 H317	GHS07
SILICATE GLASS	-	-	1-5	Not Classified	-
TITANIUM DIOXIDE	13463-67-7	236-675-5	<0.1	Acute Tox. 4 - H332 Carc. 2 - H351	GHS07 GHS08
MEQUINOL	150-76-5	205-769-8	<0.1	Acute Tox. 4 H302 Skin Sens. 1 H317 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

Description of first aid measures : Rescuers should take suitable precautions to avoid becoming casualties themselves. Remove to fresh air immediately. If signs/symptoms continue, get medical attention.

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

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Eye Contact	before reuse. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 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	
Inhalation	May cause respiratory irritation.
Skin contact	Causes skin irritation. May cause an allergic skin reaction.
Eye contact	Causes serious eye irritation.
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 foam, carbon dioxide, dry powder or water fog.
Unsuitable extinguishing media	Not known.

5.2 Special hazards arising from the substance or mixture

Specific hazards	In case of fire, toxic gases may be formed.
Hazardous combustion products	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

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.
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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	Provide adequate ventilation. Collect and place in suitable waste disposal containers and seal securely.
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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	Wear protective clothing as described in Section 8 of this safety data sheet. All handling should only take place in well-ventilated areas. Avoid contact with skin, eyes and clothing. Avoid breathing vapour/spray.
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Advice on general occupational hygiene

Do not eat, drink or smoke when using this product. Wash 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. Take off contaminated clothing and wash it before reuse.

7.2 Conditions for safe storage, including any incompatibilities

Storage precautions	Store in tightly-closed, original container in a well-ventilated place. Keep away from heat, sparks and open flame. Avoid exposure to high temperatures or direct sunlight.
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Storage temperature (°C)

0-25°C .

Storage life

Stable under normal conditions.

Incompatible materials

Incompatible with organic peroxides. Oxidizing agents, Acids, Alkalies .

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

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8.1.1 Occupational Exposure Limits

Occupational Exposure Limits						
SUBSTANCE	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m ³)	STEL (ppm)	STEL (mg/m ³)	Note
TITANIUM DIOXIDE(respirable dust)	13463-67-7		4			WEL
TITANIUM DIOXIDE(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

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	Wear tight-fitting, chemical splash goggles or face shield. 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	None known.
Hygiene measures		Do not eat, drink or smoke when using this product. Wash 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. Take off contaminated clothing and wash it before reuse.

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
Odour	Odourless
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.

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Density (g/ml)	Not available.
Relative density	1.7
Solubility(ies)	Solubility (Water) : Not available. 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.

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

Calculation method : STOT SE 3 - May cause respiratory irritation.

STOT - repeated exposure

Not classified.

Aspiration hazard

Not classified.

11.2 Other information

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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

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	Not listed

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subject to authorisation	
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-BENZOTRIAZOLE-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 concerning the export and import of hazardous chemicals	Not listed
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.
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LEGEND

Hazard Pictogram(s)



GHS07

GHS08: GHS: Health hazard

GHS09: GHS: Environment

Hazard classification

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.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

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

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Prec cautionary Statement(s)

H412: Harmful to aquatic life with long lasting effects.
P261 Avoid breathing vapour/ spray.
P264 Wash contaminated skin thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312 Call a POISON CENTRE/doctor if you feel unwell.
P321 Specific treatment (see medical advice on this label).
P302+P352 IF ON SKIN: Wash with plenty of water.
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.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing.
P403+P233 Store in a well-ventilated place. Keep container tightly closed.
P405 Store locked up.
P501 Dispose of contents/ container in accordance with local regulations.

Acronyms

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

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