

**ESTELITE POSTERIOR**

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 POSTERIOR

**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](mailto: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 Sens. 1 :May cause an allergic skin reaction.

**2.2 Label elements**

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

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## Hazard Pictogram(s)



## Signal Word(s)

GHS07

Warning

## Hazard Statement(s)

H317: May cause an allergic skin reaction.

## 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.

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

P501 Dispose of contents/ container in accordance with local regulations

**2.3 Other hazards**

None known. 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-

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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)
REACTION MASS OF SILICON DIOXIDE AND ZIRCONIUM DIOXIDE	-	910-388-1 01-2119860534-36-0000	70-90	Not Classified	-
(1-METHYLETHYLIDENE)BIS [4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE	1565-94-2	216-367-7	5-15	Skin Sens. 1 H317 Aquatic Chronic 3 H412	GHS07
2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE	109-16-0	203-652-6	1-10	Skin Irrit. 2 H315 Skin Sens. 1 H317 Eye Irrit. 2 H319	GHS07
(1-METHYLETHYLIDENE)BIS(4,1-PHENYLENEOXY-2,1-ETHANEDIYLOXY-2,1-ETHANEDIYL)BISMETHACRYLATE	41637-38-1	609-946-4	1-5	Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 Skin Sens. 1 - H317 STOT SE 3 - H335	GHS07
TITANIUM DIOXIDE	13463-67-7	236-675-5	<0.5	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	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 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..
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 : Allergic rash.

**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.

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Protective actions during Firefighting  
Special protective equipment for firefighters

Avoid breathing fire gases or vapours.  
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

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

**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

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 (8 hr TWA ppm)	LTEL (8 hr TWA mg/m <sup>3</sup> )	STEL (ppm)	STEL (mg/m <sup>3</sup> )	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**

	<p>Eye Protection</p> <p>The following protection should be worn: Chemical splash goggles. Wear eye protection with side protection (EN166).</p>
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	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 must be used if the airborne contamination exceeds the recommended occupational exposure limit.
	Thermal hazards	None known.
	Hygiene measures	Do not smoke in work area. 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. 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
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	2.1
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**

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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	Not classified.
Serious eye damage/irritation	Not classified.
Skin sensitization data	Calculation method : 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**

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**

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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 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.

**ESTELITE POSTERIOR****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

29-10-2014

Date of Revision

15-12-2022

Revision ( EU )

4

**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

Precautionary Statement(s)

P261 Avoid breathing vapours.

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.

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

P333+P313 If skin irritation or rash occurs: 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

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

## **ESTELITE POSTERIOR**

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.