

ESTELITE COLOR

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 COLOR

1.2 Relevant identified uses of the substance or mixture and uses advised againstIdentified 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

SupplierCompany 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)
Product Name ESTELITE COLOR**Hazard Pictogram(s)**

GHS07

Signal Word(s)

Warning

Hazard Statement(s)

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.

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

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

ESTELITE COLOR

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-2,1-ETHANEDIYLOXY-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)
REACTION MASS OF SILICON DIOXIDE AND ZIRCONIUM DIOXIDE	-	910-388-1 01-2119860534-36-0000	30-50	Not Classified	-
(1-METHYLETHYLIDENE)BIS(4,1-PHENYLENEOXY-2,1-ETHANEDIYLOXY-2,1-ETHANEDIYL) BISMETHACRYLATE	41637-38-1	609-946-4	20-40	Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 Skin Sens. 1 - H317 STOT SE 3 - H335	GHS07
REACTION MASS OF SILICON DIOXIDE AND TITANIUM DIOXIDE	-	-	10-20	Not Classified	-
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
7,7,9(OR 7,9,9)-TRIMETHYL-4,13-DIOXO-3,14-DIOXA-5,12-DIAZAHXADECANE-1,16-DIYL BISMETHACRYLATE	72869-86-4	276-957-5	1-10	Skin Sens. 1 H317	GHS07
(1-METHYLETHYLIDENE)BIS(4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE	1565-94-2	216-367-7	<5	Skin Sens. 1 H317 Aquatic Chronic 3 H412	GHS07
DL-BORNANE-2,3-DIONE	10373-78-1	233-814-1	<2	Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 STOT SE 3 - H335	GHS07
TITANIUM DIOXIDE	13463-67-7	236-675-5	<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

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.. Take off contaminated clothing and

ESTELITE COLOR

Eye Contact	wash it before reuse. Rinse immediately with plenty of water. 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	
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 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	When heated and in case of fire, irritating vapours/gases may be formed
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	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. Do not eat, drink or smoke when using this product. Wash at the end of each w
-------------------	---

7.2 Conditions for safe storage, including any incompatibilities

Storage precautions	Store in a cool and well-ventilated place. Store at temperatures between 0°C/32°F and 25°C/77°F. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid exposure to high temperatures or direct sunlight.
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 ³)	STEL (ppm)	STEL (mg/m ³)	Note
TITANIUM DIOXIDE (respirable dust)	13463-67-7		4			WEL

ESTELITE COLOR





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. Personal, workplace environment or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Personal protective equipment should only be used if worker exposure cannot be controlled adequately by the engineering control measures

8.2.2. Personal protection equipment

	Eye Protection	Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. Personal protective equipment for eye and face protection should comply with European Standard EN166. Unless the assessment indicates a higher degree of protection is required, the following protection should be worn: Tight-fitting safety glasses
	Skin protection	Wear appropriate clothing to prevent any possibility of skin contact. Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible. The most suitable glove should be chosen in consultation with the glove supplier/manufacturer, who can provide information about the breakthrough time of the glove material. To protect hands from chemicals, gloves should comply with European Standard EN374. Considering the data specified by the glove manufacturer, check during use that the gloves are retaining their protective properties and change them as soon as any deterioration is detected. Frequent changes are recommended. Appropriate footwear and additional protective clothing complying with an approved standard should be worn if a risk assessment indicates skin contamination is possible.
	Respiratory protection	Respiratory protection complying with an approved standard should be worn if a risk assessment indicates inhalation of contaminants is possible. Ensure all respiratory protective equipment is suitable for its intended use and is 'CE'-marked. Check that the respirator fits tightly and the filter is changed regularly. Gas and combination filter cartridges should comply with European Standard EN14387. Full face mask respirators with replaceable filter cartridges should comply with European Standard EN136. Half mask and quarter mask respirators with replaceable filter cartridges should comply with European Standard EN140
	Thermal hazards	None known.
	Hygiene measures	Provide eyewash station and safety shower. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Clean equipment and the work area every day. Good personal hygiene procedures should be implemented. Wash at the end of each work shift and before eating, smoking and using the toilet. When using do not eat, drink or smoke. Preventive industrial medical examinations should be carried out. Warn cleaning personnel of any hazardous properties of the product.

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 : White to slightly yellowish
Odour	Not available.

ESTELITE COLOR

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	1.8
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

ESTELITE COLOR

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

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 potential

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

ESTELITE COLOR

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.

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 Date of

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

First Issue

21-10-2014

Date of Revision

15-12-2022

Revision (EU)

4

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

ESTELITE COLOR

Hazard Statement(s)

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

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.

Precautionary Statement(s)

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

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.