

SAFETY DATA SHEET

ESTELITE COLOR

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 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 Chizzalunga, 1,
36066 Sandrigo, Vicenza, Italy
TEL: +39-0444-659650
FAX: +39-0444-750345

Contact person

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

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

Emergency telephone

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Not Classified

Health hazards Skin Irrit. 2 - H315: Eye Irrit. 2 - H319: Skin Sens. 1 - H317: STOT SE 3 - H335

Environmental hazards Not Classified

2.2. Label elements

Pictogram



Signal word

Warning

Hazard statements

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

ESTELITE COLOR

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

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

Supplementary precautionary statements 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.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312 Call a POISON CENTER/ doctor if you feel unwell.
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.
P405 Store locked up.

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

3.2. Mixtures

(1-METHYLETHYLIDENE)BIS(4,1-PHENYLENEOXY-2,1-ETHANEDIYLOXY-2,1-ETHANEDIYL) BISMETHACRYLATE	20-50%
CAS number: 41637-38-1	EC number: 609-946-4
Classification Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 Skin Sens. 1 - H317 STOT SE 3 - H335	
2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE	5-20%
CAS number: 109-16-0	EC number: 203-652-6
Classification Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 Skin Sens. 1 - H317	

ESTELITE COLOR

(1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE CAS number: 1565-94-2 EC number: 216-367-7	0-5%
Classification Skin Sens. 1 - H317 Aquatic Chronic 3 - H412	
TITANIUM DIOXIDE CAS number: 13463-67-7 EC number: 236-675-5	<1%
Classification Acute Tox. 4 - H332 Carc. 2 - H351	
2,6-DI-tert-BUTYL-p-CRESOL CAS number: 128-37-0 EC number: 204-881-4 M factor (Chronic) = 1	<1%
Classification Aquatic Chronic 1 - H410	

The full text for all hazard statements is displayed in Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information	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.
Ingestion	Try to induce vomiting. 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. Get medical attention if irritation persists after washing.

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

Inhalation	May cause respiratory irritation.
Skin contact	Skin irritation. Allergic rash.
Eye contact	May cause severe eye irritation.

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

Notes for the doctor	No specific recommendations.
-----------------------------	------------------------------

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Extinguish with foam, carbon dioxide, dry powder or water fog.

5.2. Special hazards arising from the substance or mixture

Specific hazards In case of fire, toxic gases may be formed.

ESTELITE COLOR

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.

6.2. Environmental precautions

Environmental precautions Avoid the spillage or runoff entering drains, sewers or watercourses.

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. Collect and place in suitable waste disposal containers and seal securely.

6.4. Reference to other sections

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. Keep away from heat, sparks and open flame. Avoid contact with skin, eyes and clothing. Avoid breathing vapour/spray.

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 dry and cool place. Store at temperatures between 0°C/32°F and 25°C/77°F. Keep away from heat, sparks and open flame. Protect from light.

7.3. Specific end use(s)

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

Occupational exposure limits

TITANIUM DIOXIDE

Long-term exposure limit (8-hour TWA): WEL 4 mg/m³ respirable dust

Long-term exposure limit (8-hour TWA): WEL 10 mg/m³ inhalable dust

2,6-DI-tert-BUTYL-p-CRESOL

Long-term exposure limit (8-hour TWA): WEL 10 mg/m³

WEL = Workplace Exposure Limit

ESTELITE COLOR

8.2. Exposure controls

Appropriate engineering controls	Provide adequate general and local exhaust ventilation.
Eye/face protection	The following protection should be worn: Chemical splash goggles.
Hand protection	Wear protective gloves.
Other skin and body protection	Wear appropriate clothing to prevent any possibility of skin contact.
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.
Respiratory protection	No specific recommendations. Respiratory protection may be required if excessive airborne contamination occurs.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance	Paste
Colour	Blue, Gray, Lavender, Ochre, Yellow, Red, Pink, White, Yellow white, Dark brown, Clear
Odour	Characteristic
Odour threshold	Not available.
pH	Technical impossibility to obtain the data.
Melting point	Not available.
Initial boiling point and range	Not available.
Flash point	Not applicable.
Evaporation rate	Not available.
Evaporation factor	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	Not applicable.
Other flammability	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	1.7
Solubility(ies)	Not available.
Partition coefficient	Not available.
Auto-ignition temperature	Not available.
Decomposition Temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.

ESTELITE COLOR

Oxidising properties Not available.

9.2. Other information

Other information Not available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity There are no known reactivity hazards associated with this product.

10.2. Chemical stability

Stability Stable at normal ambient temperatures and when used as recommended.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions Not known.

10.4. Conditions to avoid

Conditions to avoid Keep away from heat, sparks and open flame. Protect against direct sunlight.

10.5. Incompatible materials

Materials to avoid No specific material or group of materials is likely to react with the product to produce a hazardous situation.

10.6. Hazardous decomposition products

Hazardous decomposition products Heating may generate the following products: Toxic gases or vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - oral

Notes (oral LD₅₀) Not available.

Acute toxicity - dermal

Notes (dermal LD₅₀) Not available.

Acute toxicity - inhalation

Notes (inhalation LC₅₀) Not available.

Skin corrosion/irritation

Skin corrosion/Irritation Skin Irrit. 2 - H315, Causes skin irritation.

Animal data

Not available.

Serious eye damage/irritation

Serious eye damage/irritation Eye Irrit. 2 - H319 Causes serious eye irritation.

Respiratory sensitisation

Respiratory sensitisation Not available.

Skin sensitisation

Skin sensitisation Skin Sens. 1 - H317 May cause an allergic skin reaction.

Germ cell mutagenicity

Genotoxicity - in vitro Not available.

ESTELITE COLOR

Genotoxicity - in vivo	Not available.
<u>Carcinogenicity</u>	
Carcinogenicity	Not available.
IARC carcinogenicity	Some of the ingredients are listed or exempt.
NTP carcinogenicity	Some of the ingredients are listed or exempt.
<u>Reproductive toxicity</u>	
Reproductive toxicity - fertility	Not available.
Reproductive toxicity - development	Not available.
<u>Specific target organ toxicity - single exposure</u>	
STOT - single exposure	STOT SE 3 - H335 May cause respiratory irritation.
<u>Specific target organ toxicity - repeated exposure</u>	
STOT - repeated exposure	Not available.
<u>Aspiration hazard</u>	
Aspiration hazard	Not available.

TITANIUM DIOXIDE

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

Carcinogenicity

IARC carcinogenicity IARC Group 3 Not classifiable as to its carcinogenicity to humans.
NTP carcinogenicity Reasonably anticipated to be a human carcinogen.
OSHA Carcinogenicity Not listed.

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

Persistence and degradability No data available.

12.3. Bioaccumulative potential

ESTELITE COLOR

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

Results of PBT and vPvB assessment This product does not contain any substances classified as PBT or vPvB.

12.6. Other adverse effects

Other adverse effects Not known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal methods Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

SECTION 14: Transport information

General Not regulated.

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 MARPOL and the IBC Code

Transport in bulk according to Annex II of MARPOL 73/78 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 (EC) No 1907/2006 (REACH).
(EC) No 1272/2008 (CLP).
(EU) No 2015/830.

15.2. Chemical safety assessment

ESTELITE COLOR

No chemical safety assessment has been carried out.

SECTION 16: Other information

Classification procedures according to Regulation (EC) 1272/2008	Skin Irrit. 2 - H315: Calculation method. Skin Sens. 1 - H317: Calculation method. Eye Irrit. 2 - H319: Calculation method. STOT SE 3 - H335: Calculation method.
Training advice	Ensure operatives are trained to minimise exposure. Only trained personnel should use this material.
Revision comments	
Revision date	15/09/2018
Revision	3
Hazard statements in full	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.

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 information.