

## SAFETY DATA SHEET ESTECEM II PLUS PASTE A/B

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

**Product name** ESTECEM II PLUS PASTE A/B

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Identified uses** **【Medical Device】** Adhesive resin cement. For dental professionals only.

**Uses Not Recommended** Use only for intended applications.

#### 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](mailto: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

**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.

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<b>Precautionary statements</b>	<p>P261 Avoid breathing vapours.</p> <p>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</p> <p>P333+P313 If skin irritation or rash occurs: Get medical advice/ attention.</p> <p>P337+P313 If eye irritation persists: Get medical advice/ attention.</p> <p>P501 Dispose of contents/ container in accordance with local regulations.</p>
<b>Contains</b>	<p>(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, BENZOYL PEROXIDE, 2,2'-[(4-METHYLPHENYL)IMINO]BIETHANOL</p>
<b>Supplementary precautionary statements</b>	<p>P264 Wash contaminated skin thoroughly after handling.</p> <p>P272 Contaminated work clothing should not be allowed out of the workplace.</p> <p>P302+P352 IF ON SKIN: Wash with plenty of water.</p> <p>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P321 Specific treatment (see medical advice on this label).</p> <p>P332+P313 If skin irritation occurs: Get medical advice/ attention.</p> <p>P362+P364 Take off contaminated clothing and wash it before reuse.</p>

### 2.3. Other hazards

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

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

<b>SILICA-ZIRCONIA FILLER</b>	<b>60-80%</b>
CAS number: - EC number / REACH Registration No.: 910-388-1 / 01-2119860534-36-0000	
Classification : Substance not classified as hazardous	
<b>(1-METHYLETHYLIDENE)BIS(4,1-PHENYLENEOXY-2,1-ETHANEDIYLOXY-2,1-ETHANEDIYL) BISMETHACRYLATE</b>	<b>5-15%</b>
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	
<b>2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE</b>	<b>5-15%</b>
CAS number: 109-16-0 EC number: 203-652-6	
Classification : Skin Irrit.2 - H315, Eye Irrit.2 - H319, Skin Sens.1 - H317	
<b>(1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY (2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE</b>	<b>1-5%</b>
CAS number: 1565-94-2 EC number: 216-367-7	
Classification : Skin Sens.1 - H317, Aquatic Chronic 3 - H412	
<b>SILICON DIOXIDE</b>	<b>1-5%</b>
CAS number: 112945-52-5 EC number.: 601-216-3	
Classification : Substance not classified as hazardous	

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<b>TITANIUM DIOXIDE</b>	<b>&lt;1%</b>
CAS number: 13463-67-7    EC number: 236-675-5	
Classification : Acute Tox. 4 - H332	
<b>BENZOYL PEROXIDE</b>	<b>&lt;1%</b>
CAS number: 94-36-0    EC number: 202-327-6	
Classification : Org. Perox. B - H241, Eye Irrit. 2 - H319, Skin Sens. 1 - H317	
<b>2,6-DI-tert-BUTYL-p-CRESOL</b>	<b>&lt;0.1%</b>
CAS number: 128-37-0    EC number: 204-881-4	
Classification : Aquatic Chronic 1 H410 (M Factor(Chronic) =1)	
<b>MEQUINOL</b>	<b>&lt;0.1%</b>
CAS number: 150-76-5    EC number: 205-769-8	
Classification : Acute Tox. 4- H302, Eye Irrit. 2 - H319, Skin Sens. 1 - H317	
<b>1,1-(1,1-DIMETHYL-3-METHYLENE-1,3-PROPANEDIYL)BISBENZENE</b>	<b>&lt;0.1%</b>
CAS number : 6362-80-7                      EG number: 228-846-8	
Classification : Acute Tox.4- H302 , Skin Sens. 1 - H317, STOT.RE. 2- H373, Aquatic Acute. 1-H400, (M Factor(Acute)=10), Aquatic Chronic. 1-H410, (M Factor(Chronic)=1)	

Voluntary Disclosure according to ISO4049:2019

Contains no non-classified vPvB substances.

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

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

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

<b>General information</b>	Move affected person to fresh air at once. Get medical attention if any discomfort continues.
<b>Inhalation</b>	Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Get medical attention if any discomfort continues.
<b>Ingestion</b>	Rinse mouth thoroughly with water. Give plenty of water to drink. Get medical attention if any discomfort continues.
<b>Skin contact</b>	Wash skin thoroughly with soap and water. Take off contaminated clothing and wash it before reuse.
<b>Eye contact</b>	Make sure to remove any contact lenses from the eyes before rinsing. Promptly wash eyes with plenty of water while lifting the eye lids. 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

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**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 alcohol-resistant 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.

**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. Keep up-wind to avoid fumes. Move containers from fire area if it can be done without risk. Containers close to fire should be removed or cooled with water. No smoking, sparks, flames or other sources of ignition near spillage.

**Special protective equipment for firefighters** Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing.

## **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. No smoking, sparks, flames or other sources of ignition near spillage.

### **6.2. Environmental precautions**

**Environmental precautions** Avoid discharge into drains or watercourses or onto the ground.

### **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. Keep combustible materials away from spillage. Absorb in vermiculite, dry sand or earth and place into containers. Avoid the spillage or runoff entering drains, sewers or watercourses. Use only non-sparking tools.

### **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** All handling should only take place in well-ventilated areas. Keep away from heat, sparks and open flame. Good personal hygiene procedures should be implemented. Wash hands and any other contaminated areas of the body with soap and water before leaving the work site. Take any precaution to avoid mixing with combustibles and reducing agents.

### **7.2. Conditions for safe storage, including any incompatibilities**

**Storage precautions** Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Protect from sunlight. Store at temperatures between 0°C/32°F and 10°C/50°F.

### **7.3. Specific end use(s)**

The identified uses for this product are detailed in Section 1.2.

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### 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/m<sup>3</sup> respirable dust

Long-term exposure limit (8-hour TWA): WEL 10 mg/m<sup>3</sup> inhalable dust

##### BENZOYL PEROXIDE

Long-term exposure limit (8-hour TWA): WEL 5 mg/m<sup>3</sup>

WEL = Workplace Exposure Limit

#### 8.2. Exposure controls

**Appropriate engineering controls** Provide adequate general and local exhaust ventilation. Observe any occupational exposure limits for the product or ingredients.

**Eye/face protection** The following protection should be worn: Chemical splash goggles.

**Skin protection** Wear protective gloves.

**Other skin and body protection** Wear appropriate clothing to prevent any possibility of skin contact.

**Hygiene measures** Use engineering controls to reduce air contamination to permissible exposure level. Provide eyewash station and safety shower. Do not smoke in work area. Promptly remove any clothing that becomes contaminated. Wash promptly with soap and water if skin becomes contaminated. Wash at the end of each work shift and before eating, smoking and using the toilet. When using do not eat, drink or smoke.

**Respiratory protection** If ventilation is inadequate, suitable respiratory protection must be worn.

**8.3 Environmental Exposure Controls** Avoid release to the environment.

### SECTION 9: Physical and Chemical Properties

#### 9.1. Information on basic physical and chemical properties

<b>Appearance</b>	Paste
<b>Colour</b>	Clear , white to brown
<b>Odour</b>	Characteristic
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point</b>	Not available.
<b>Initial boiling point and range</b>	Not available.
<b>Flash point</b>	Not applicable.
<b>Evaporation rate</b>	Not available.
<b>Evaporation factor</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	Not available.
<b>Vapour pressure</b>	Not available.

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Vapour density	Not available.
Relative density	Not determined.
Solubility(ies)	Not available.
Partition coefficient	Not available.
Auto-ignition temperature	Not available.
Decomposition Temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
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. See the other subsections of this section for further details.

### 10.2. Chemical stability

**Stability** Stable under the prescribed storage conditions.

### 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** Flammable/combustible materials. Strong reducing agents.

### 10.6. Hazardous decomposition products

**Hazardous decomposition products** Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours. Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>).

## **SECTION 11: Toxicological information**

### 11.1. Information on toxicological effects

**Routes of exposure** Skin , Eyes , Ingestion , Inhalation , Health effects: See section 4.2.

#### Acute toxicity - oral

**Notes (oral LD<sub>50</sub>)** Not available.

#### Acute toxicity - dermal

**Notes (dermal LD<sub>50</sub>)** Not available.

#### Acute toxicity - inhalation

**Notes (inhalation LC<sub>50</sub>)** Not available.

#### Skin corrosion/irritation

**Skin corrosion/irritation** Causes skin irritation.

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<b>Animal data</b>	Not available.
<b><u>Serious eye damage/irritation</u></b>	
<b>Serious eye damage/irritation</b>	Causes serious eye irritation.
<b><u>Respiratory sensitisation</u></b>	
<b>Respiratory sensitisation</b>	Not available.
<b><u>Skin sensitisation</u></b>	
<b>Skin sensitisation</b>	May cause an allergic skin reaction.
<b><u>Germ cell mutagenicity</u></b>	
<b>Genotoxicity - in vitro</b>	Not available.
<b>Genotoxicity - in vivo</b>	Not available.
<b><u>Carcinogenicity</u></b>	
<b>Carcinogenicity</b>	Not available.
<b>IARC carcinogenicity</b>	Some of the ingredients are listed or exempt.
<b>NTP carcinogenicity</b>	Some of the ingredients are listed or exempt.
<b><u>Reproductive toxicity</u></b>	
<b>Reproductive toxicity - fertility</b>	Not available.
<b>Reproductive toxicity - development</b>	Not available.
<b><u>Specific target organ toxicity - single exposure</u></b>	
<b>STOT - single exposure</b>	Not available.
<b><u>Specific target organ toxicity - repeated exposure</u></b>	
<b>STOT - repeated exposure</b>	Not available.
<b><u>Aspiration hazard</u></b>	
<b>Aspiration hazard</b>	Not available.

### TITANIUM DIOXIDE

#### Acute toxicity - inhalation

**ATE inhalation** 1.5  
(dusts/mists mg/l)

#### Carcinogenicity

**IARC carcinogenicity** IARC Group 2B Possibly carcinogenic to humans.  
**NTP carcinogenicity** Reasonably anticipated to be a human carcinogen.  
**OSHA Carcinogenicity** Not listed.

### BENZOYL PEROXIDE

#### 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.

### 11.2 Other information

**Route(s) of entry** Skin, Eyes, Ingestion, Inhalation, Health effects: See section 4.2.  
Endocrine disrupting properties: Not known.

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### SECTION 12: Ecological Information

#### 12.1 Toxicity

Toxicity - Aquatic invertebrates	Not classified.
Toxicity - Fish	Not classified.
Toxicity - Algae	Not classified.
Toxicity - Sediment Compartment	Not classified.
Toxicity - Terrestrial Compartment	Not classified.

#### 12.2 Persistence and degradability

Not known.

#### 12.3 Bioaccumulative potential

Not known.

#### 12.4 Mobility in soil

Not known.

#### 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

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** 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.



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### 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

**EU legislation** (EC) No 1907/2006 (REACH).  
(EC) No 1272/2008 (CLP).  
(EU) No 2015/830.  
Directive 93/42/EEC

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS), usually if they are in the finished state and intended for the final user. The product is classified according to the CLP regulation.

#### 15.2. Chemical safety assessment

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.

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

#### **Revision comments**

**Date of First Issue** 01/11/2020

**Date of Revision** 15/12/2022

**Revision ( UK )** 2

**Hazard statements in full** H241 Heating may cause a fire or explosion.  
H301 Toxic if swallowed.  
H311 Toxic in contact with skin.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H331 Toxic if inhaled.  
H332 Harmful if inhaled.  
H335 May cause respiratory irritation.  
H351 Suspected of causing cancer.  
H373 May cause damage to organs through prolonged or repeated exposure.  
H412 Harmful to aquatic life with long lasting effects.

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