SAFETY DATA SHEET
ESTECEM Ⅱ PASTE A/B

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

1.1. Product identifier

Product name ESTECEM Ⅱ 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

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.

Precautionary statements	P261 Avoid breathing vapours. 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. 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, BENZOYL PEROXIDE, 2,2'-[(4-METHYLPHENYL)IMINO]BISETHANOL
Supplementary precautionary statements	P264 Wash contaminated skin thoroughly after handling. P272 Contaminated work clothing should not be allowed out of the workplace. 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. P321 Specific treatment (see medical advice on this label). P332+P313 If skin irritation occurs: Get medical advice/ attention. P362+P364 Take off contaminated clothing and wash it before reuse.

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

SILICA-ZIRCONIA FILLER **60-80%**
CAS number: ¯ EC number／REACH Registration No.: 910-388-1 / 01-2119860534-36-0000
Classification : Substance not classified as hazardous

(1-METHYLETHYLIDENE)BIS(4,1-PHENYLENEOXY-2,1-ETHANEDIYLOXY-2,1-ETHANEDIYL) BISMETHACRYLATE **5-15%**
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 **5-15%**
CAS number: 109-16-0 EC number: 203-652-6
Classification : Skin Irrit.2 - H315, Eye Irrit.2 - H319, Skin Sens.1 - H317

(1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY (2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE **1-5%**
CAS number: 1565-94-2 EC number: 216-367-7
Classification : Skin Sens.1 - H317, Aquatic Chronic 3 - H412

SILICON DIOXIDE **1-5%**
CAS number: 112945-52-5 EC number.: 601-216-3
Classification : Substance not classified as hazardous

TITANIUM DIOXIDE	**<1%**
CAS number: 13463-67-7 EC number: 236-675-5	
Classification : Acute Tox. 4 - H332	

BENZOYL PEROXIDE	**<1%**
CAS number: 94-36-0 EC number: 202-327-6	
Classification : Org. Perox. B - H241, Eye Irrit. 2 - H319, Skin Sens. 1 - H317	

2,6-DI-tert-BUTYL-p-CRESOL	**<0.1%**
CAS number: 128-37-0 EC number: 204-881-4	
Classification : Aquatic Chronic 1 H410 (M Factor(Chronic) =1)	

MEQUINOL	**<0.1%**
CAS number: 150-76-5 EC number: 205-769-8	
Classification : Acute Tox. 4- H302, Eye Irrit. 2 - H319, Skin Sens. 1 - H317	

1,1-(1,1-DIMETHYL-3-METHYLENE-1,3-PROPANEDIYL)BISBENZENE	**<0.1%**
CAS number : 6362-80-7 EG number: 228-846-8	
Classification : Acute Tox.4- H302 , Skin Sens. 1 - H317, STOT.RE. 2- H373, Aqatic Acute. 1-H400,（M Factor(Acute)=10), Aqatic Chronic. 1-H410,（M Factor(Chronic)=1）	

Voluntary Discloure 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

General information Move affected person to fresh air at once. Get medical attention if any discomfort continues.

Inhalation 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.

Ingestion Rinse mouth thoroughly with water. Give plenty of water to drink. Get medical attention if any discomfort continues.

Skin contact Wash skin thoroughly with soap and water. Take off contaminated clothing and wash it before reuse.

Eye contact 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

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.

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

BENZOYL PEROXIDE

Long-term exposure limit (8-hour TWA): WEL 5 mg/m³
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

Appearance	Paste
Colour	Clear , white to brown
Odour	Characteristic
Odour threshold	Not available.
pH	Not available.
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 available.
Vapour pressure	Not available.

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 (CO2).

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_{50})	Not available.

Acute toxicity - dermal

Notes (dermal LD_{50})	Not available.

Acute toxicity - inhalation

Notes (inhalation LC_{50})	Not available.

Skin corrosion/irritation

Skin corrosion/irritation	Causes skin irritation.

Animal data	Not available.

Serious eye damage/irritation

Serious eye damage/irritation	Causes serious eye irritation.

Respiratory sensitisation

Respiratory sensitisation	Not available.

Skin sensitisation

Skin sensitisation	May cause an allergic skin reaction.

Germ cell mutagenicity

Genotoxicity - in vitro	Not available.
Genotoxicity - in vivo	Not available.

Carcinogenicity

Carcinogenicity	Not available.
IARC carcinogenicity	Some of the ingredients are listed or exempt.
NTP carcinogenicity	Some of the ingredients are listed or exempt.

Reproductive toxicity

Reproductive toxicity - fertility	Not available.
Reproductive toxicity - development	Not available.

Specific target organ toxicity - single exposure

STOT - single exposure	Not available.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure	Not available.

Aspiration hazard

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.

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.

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.

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	20/12/2016
Date of Revision	15/12/2022
Revision (UK)	4
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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