

**ESTEC EM II PLUS PASTE A**

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 ESTEC EM II PLUS PASTE A

**1.2 Relevant identified uses of the substance or mixture and uses advised against**Identified Use(s) **【Medical Device】** Adhesive resin cement. For dental professionals only.

Uses Advised Against 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  
 E-mail <https://tokuyama-dental.com/contact/>

**Supplier**

Company Identification Tokuyama Dental Italy S.r.l.  
 Address of Supplier Via Chizzalunga, 1, 36066 Sandrigo, Vicenza, Italy  
 Postal code 36066  
 Telephone: +39-0444-659650  
 Fax +39-0444-750345  
 E-mail <https://tokuyama-dental.com/contact/>

**1.4 Emergency telephone number**

Emergency Phone No. 018 092 566  
 Contact The National Poisons Information Centre of Ireland  
 Beaumont Hospital  
 PO Box 1297, Beaumont Road, Dublin, Ireland.  
 Members of Public : +353 (1) 809 2166.  
 (8.00 a.m. to 10.00 p.m. 7 days a week)  
 Healthcare Professionals : +353 (1) 809 2566 (24 hour service)  
 Email : [chemicalsinfo@beaumont.ie](mailto:chemicalsinfo@beaumont.ie)

**National response centre**

Address Poisons Information Centre of Ireland Beaumont Hospital, PO Box 1297, Beaumont Road,  
 Dublin, Ireland.

Emergency Phone No. +353 01 809 2566 (24 hours)

**SECTION 2: HAZARDS IDENTIFICATION****2.1 Classification of the substance or mixture**

Regulation (EC) No. 1272/2008 (CLP) Skin Irrit. 2 :Causes skin irritation.  
 Skin Sens. 1 :May cause an allergic skin reaction.  
 Eye Irrit. 2 :Causes serious eye irritation.  
 Carc. 1B :May cause cancer.

**2.2 Label elements**

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

Product Name ESTEC EM II PLUS PASTE A  
 (Contains: N,N-dimethyl-p-toluidine;  
 (1-methylethylidene)bis (4,1-phenyleneoxy- 2,1-ethanedioxy-2,1-ethanediyl) bismethacrylate  
 2,2'-ethylenedioxydiethyl dimethacrylate;  
 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate)

**Hazard Pictogram(s)**

GHS08



GHS07

**Signal Word(s)**

Danger

**Hazard Statement(s)**

H315: Causes skin irritation.  
 H317: May cause an allergic skin reaction.  
 H319: Causes serious eye irritation.  
 H350: May cause cancer.

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## Precautionary Statement(s)

P201: Obtain special instructions before use.  
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 in accordance with local, state or national legislation.  
Not applicable.

## Unique Formula Identifier (UFI):

**2.3 Other hazards**

PBT assessment : This product does not contain any substances classified as PBT or vPvB.  
Endocrine disrupting properties : 128-37-0 (Under evaluation) (<0.1%)

**2.4 Additional Information**

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)
Silica-Zirkonia Filler	-	910-388-1 01-2119860534-36-0000	60-80	Not classified	None
(1-methylethylidene)bis (4,1-phenyleneoxy-2,1-ethanedioxy-2,1-ethanedioyl) bismethacrylate	41637-38-1	609-946-4	5-15	Skin Irrit. 2 H315 Skin Sens. 1 H317 Eye Irrit. 2 H319 STOT SE 3 H335	GHS07
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0	203-652-6	5-15	Skin Irrit. 2 H315 Skin Sens. 1B H317 Eye Irrit. 2 H319	GHS07
(1-methylethylidene)bis[4,1-phenyleneoxy (2-hydroxy-3,1-propanedioyl)] bismethacrylate	1565-94-2	216-367-7	1-5	Skin Sens. 1 H317 Aquatic Chronic 3 H412	GHS07
AMORPHOUS SILICA	112945-52-5	231-545-4	1-5	Not classified	None
titanium dioxide	13463-67-7	236-675-5	<1	Acute Tox. 4 H332	GHS08
2,2'-[(4-methylphenyl)imino]bisethanol	3077-12-1	221-359-1	<1	Skin Sens. 1 H317 Eye Irrit. 2 H319 Aquatic Chronic 3 H412	GHS07
N,N-dimethyl-p-toluidine	99-97-8	202-805-4	<0.5	Acute Tox. 3 H301 Acute Tox. 4 H332 Carc. 1B H350 STOT RE 2 H373 Aquatic Chronic 3 H412	GHS06 GHS08 GHS07
1,1'-(1,1-dimethyl-3-methylene-1,3-propanedioyl)bisbenzene	6362-80-7	228-846-8	<0.1	Acute Tox. 4 H302 Skin Sens. 1 H317 STOT RE 2 H373 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	GHS08 GHS07 GHS09
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 Limit	M-factor	ATE
titanium dioxide	13463-67-7			Acute Tox. 4 (H332) : 11
N,N-dimethyl-p-toluidine	99-97-8			Acute Tox. 3 (H301) : 140 Acute Tox. 4 (H332) : 1.4 Dust
1,1'-(1,1-dimethyl-3-methylene-1,3-propanedioyl)bisbenzene	6362-80-7		Aquatic Acute 1: 10	Acute Tox. 4 (H302) : 500
mequinol	150-76-5			Acute Tox. 4 (H302) : 500

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.

**ESTEC EM II PLUS PASTE A****SECTION 4: FIRST AID MEASURES****4.1 Description of first aid measures**

General	Remove to fresh air immediately. IF exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell.
Inhalation	Remove to fresh air immediately. Keep warm and at rest. Get medical advice/attention if you feel unwell.
Skin Contact	Wash affected area with plenty of soap and water. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical advice/attention. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Eye Contact	Rinse mouth. Give plenty of water to drink. If signs/symptoms continue, get medical attention.
Ingestion	Rescuers should take suitable precautions to avoid becoming casualties themselves.
Advice for first aider	

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

Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause cancer.

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

No specific recommendations. Treat symptomatically.

**SECTION 5: FIREFIGHTING MEASURES****5.1 Extinguishing media**

Suitable Extinguishing media	Alcohol resistant foam. Carbon dioxide. Water fog or dry powder.
Unsuitable extinguishing media	No information available

**5.2 Special hazards arising from the substance or mixture**

In case of fire: Toxic gas may be formed. Combustion or thermal decomposition will evolve toxic vapours. Toxic gases/vapours : Carbon monoxide, Carbon dioxide

**5.3 Advice for firefighters**

Avoid breathing gas. Avoid breathing vapours. Keep upwind. Portable containers should be moved if possible and without risk. Keep fire exposed containers cool by spraying with water. No open flames, no sparks and no smoking. Fire fighters should wear complete protective clothing including self-contained breathing apparatus.

**SECTION 6: ACCIDENTAL RELEASE MEASURES****6.1 Personal precautions, protective equipment and emergency procedures**

Wear protective clothing as per section 8. No open flames, no sparks and no smoking.

**6.2 Environmental precautions**

Do not allow to enter drains, sewers or watercourses.

**6.3 Methods and material for containment and cleaning up**

Eliminate sources of ignition. No open flames, no sparks and no smoking. Provide adequate ventilation. Keep away from clothing and other combustible materials. Adsorb spillages onto sand, earth or any suitable adsorbent material. Place in appropriate container. Avoid run off to waterways and sewers. Use non-sparking tools.

**6.4 Reference to other sections**

See Also Section 8, 13.

**SECTION 7: HANDLING AND STORAGE****7.1 Precautions for safe handling**

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use only in well-ventilated areas. Avoid breathing vapours. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Wear protective clothing as per section 8. Wash hands before breaks and after work. Wash the contaminated area of body with soap and fresh water. Take any precaution to avoid mixing with combustibles.

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

Store locked up. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep cool. Protect from sunlight.

Storage temperature 0 - 10°C

Storage life Stable under the prescribed storage conditions.

Incompatible materials Flammable or combustible materials. Strong reducing agent.

**7.3 Specific end use(s)**

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【Medical Device】 Adhesive resin cement. 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
2,6-Ditertiary-butyl-para- cresol (Butylated hydroxytoluene (BHT))	128-37-0		2			
Titanium dioxide - total inhalable dust	13463-67-7		10			
Titanium dioxide - respirable dust	13463-67-7		4			
4-Methoxyphenol (Mequinol)	150-76-5		5			

Region Source

EU Indicative Occupational Exposure Limit Value





Ireland Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations (2001-2021) and Safety,  
Health and Welfare at Work (Carcinogens) Regulations 2024, Ireland

Remark Notes

**8.2 Exposure controls****8.2.1. Appropriate engineering controls**

Provide adequate ventilation, including appropriate local extraction. Provide adequate ventilation to ensure that the occupational exposure limit is not exceeded.

**8.2.2. Personal protection equipment**

	Eye Protection	Wear eye protection with side protection (EN ISO 16321-1). Wear chemical resistant protective eye glasses. Goggles.
	Skin protection	Wear protective clothing and gloves: 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. Breakthrough time of the glove material: refer to the information provided by the gloves' producer. Gloves should be changed regularly to avoid permeation problems. Wear suitable protective clothing. (Avoid contact with skin.)
	Respiratory protection	Wear a suitable respirator if the ventilation is not sufficient to keep the solvent vapour concentration below the occupational limit values.
	Thermal hazards	A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.
	Hygiene Measures	Provide adequate ventilation, including appropriate local extraction, to ensure that the occupational exposure limit is not exceeded. A washing facility/water for eye and skin cleaning purposes should be present. Remove contaminated clothing immediately. After contact with skin, wash immediately with plenty of soap and water. Wash hands before eating, drinking or smoking. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product.

**8.2.3. Environmental Exposure Controls**

Avoid release to the environment.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES****9.1 Information on basic physical and chemical properties**

Physical state	paste. (Liquid.)
Colour	Clear, White - Brown
Odour	Characteristic
Melting point/freezing point	Not known.
Boiling point or initial boiling point and	Not known.

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boiling range	
Flammability	Not applicable.
Lower and upper explosion limit	Not known.
Flash Point	Not known.
Auto-ignition temperature	Not known.
Decomposition Temperature	Not known.
pH	Not known.
Kinematic Viscosity	Not known.
Solubility	Solubility (Water) : Not known. Solubility (Other) : Not known.
Partition coefficient n-octanol/water (log value)	Not known.
Vapour pressure	Not known.
Density and/or relative density	Not known.
Relative vapour density	Not known.
Particle characteristics	Not known.
<b>9.2 Other information</b>	None.

**SECTION 10: STABILITY AND REACTIVITY**

<b>10.1 Reactivity</b>	None anticipated. See the other subsections of this section for further details.
<b>10.2 Chemical Stability</b>	Stable under the prescribed storage conditions.
<b>10.3 Possibility of hazardous reactions</b>	Not known.
<b>10.4 Conditions to avoid</b>	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep away from direct sunlight.
<b>10.5 Incompatible materials</b>	Flammable or combustible materials. Strong reducing agent.
<b>10.6 Hazardous decomposition products</b>	Combustion or thermal decomposition will evolve toxic vapours. Toxic gases/vapours : Carbon monoxide, Carbon dioxide

**SECTION 11: TOXICOLOGICAL INFORMATION**

<b>11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008</b>	
Acute toxicity - Ingestion	Calculation method : Not classified. Based on available data, the classification criteria are not met.
Acute toxicity - Skin Contact	Calculation method : Not classified. Based on available data, the classification criteria are not met.
Acute toxicity - Inhalation	Calculation method : Not classified. Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Calculation method : Causes skin irritation.
Serious eye damage/irritation	Calculation method : Causes serious eye irritation.
Skin sensitization data	Calculation method : May cause an allergic skin reaction.
Respiratory sensitization data	Calculation method : Not classified. Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Calculation method : Not classified. Based on available data, the classification criteria are not met.
Carcinogenicity	Calculation method : May cause cancer. titanium dioxide (13463-67-7) IARC Classification: Group 2B. NTP carcinogenicity : Not listed . 2,6-di-tert-butyl-p-cresol(128-37-0) IARC Classification: Group 3. NTP carcinogenicity : Not listed . N,N-dimethyl-p-toluidine (99-97-8) IARC Classification: Group 2B. NTP carcinogenicity : Not listed .
Reproductive toxicity	Calculation method : Not classified.

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Lactation	Based on available data, the classification criteria are not met. Calculation method : Not classified.
STOT - single exposure	Based on available data, the classification criteria are not met. Calculation method : Not classified.
STOT - repeated exposure	Based on available data, the classification criteria are not met. Calculation method : Not classified.
Aspiration hazard	Based on available data, the classification criteria are not met. Calculation method : Not classified.
<b>11.2 Information on other hazards</b>	Based on available data, the classification criteria are not met.
Route(s) of entry	Skin, Eyes, Ingestion, Inhalation, Health effects: See section 4.2.
Endocrine disrupting properties	128-37-0 (Under evaluation) (<0.1%)

**SECTION 12: ECOLOGICAL INFORMATION****12.1 Toxicity**

Calculation method : Not classified. Based on available data, the classification criteria are not met.

Toxicity - Aquatic invertebrates	Data lacking.
Toxicity - Fish	Data lacking.
Toxicity - Algae	Data lacking.
Toxicity - Sediment Compartment	Data lacking.
Toxicity - Terrestrial Compartment	Data lacking.

**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**

128-37-0 (Under evaluation) (&lt;0.1%)

**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**

Not classified as hazardous for transport.

**14.1 UN number or ID 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**

Environmental hazards Not classified as a Marine Pollutant.

**14.6 Special precautions for user**

Special precautions for user Not known.

**14.7 Maritime transport in bulk according to IMO instruments**

No information available

**ESTEC EM II PLUS PASTE A****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), Silicon dioxide(7631-86-9), titanium dioxide (13463-67-7), (1-methylethylidene)bis (4,1-phenyleneoxy- 2,1-ethanedioxy-2,1-ethanediyl) bismethacrylate (41637-38-1)
Regulation (EU) N° 2019/1021 of the European Parliament and of the Council on persistent organic pollutants	Not listed
Regulation (EC) N° 2024/590 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:

Date of Issue : 01-09-2025

Revision ( EN ): 1

**LEGEND**

Hazard Pictogram(s)



GHS08



GHS07

Hazard classification

GHS06: GHS: Skull and crossbones

GHS09: GHS: Environment

Acute Tox. 3 : Acute toxicity, Category 3

Acute Tox. 4 : Acute toxicity, Category 4

Skin Irrit. 2 : Skin corrosion/irritation, Category 2

Skin Sens. 1 : Skin sensitization, Category 1

Skin Sens. 1B : Skin sensitization, Category 1B

Eye Irrit. 2 : Serious eye damage/irritation, Category 2

Acute Tox. 4 : Acute toxicity, Category 4

STOT SE 3 : Specific target organ toxicity — single exposure, Category 3

Carc. 1B : Carcinogenicity, Category 1B

STOT RE 2 : Specific target organ toxicity — repeated exposure, Category 2

Aquatic Acute 1 : Hazardous to the aquatic environment, Acute, Category 1

Aquatic Chronic 1 : Hazardous to the aquatic environment, Chronic, Category 1

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## Hazard Statement(s)

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

H301: Toxic if swallowed.

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.

H350: May cause cancer.

H373: May cause damage to organs through prolonged or repeated exposure.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

H412: Harmful to aquatic life with long lasting effects.

## Precautionary Statement(s)

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P261: Avoid breathing vapours.

P264: Wash hands and exposed skin thoroughly after handling.

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.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308+P313: IF exposed or concerned: Get medical advice/attention.

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.

P501: Dispose of contents in accordance with local, state or national legislation.

## Acronyms

ATE : Acute Toxicity Estimate

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

LTCL : Long term exposure limit

PBT : Persistent, Bioaccumulative and Toxic

PNEC : Predicted No Effect Concentration

REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals

STEL : Short term exposure limit

STOT : Specific Target Organ Toxicity

vPvB : very Persistent and very Bioaccumulative

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

## Key literature references and sources for data used to compile the SDS

## Training Advice

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

## 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.

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