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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****· 1.1 Product identifier****· Trade name: ESTENIA C&B ; BODY****· Article number: 095-B****· Registration number** Not applicable**· 1.2 Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

**· Application of the substance / the mixture** Dental materials**· 1.3 Details of the supplier of the safety data sheet****· Supplier :**Kuraray Europe GmbH  
Philipp-Reis-Str. 4,  
65795 Hattersheim am Main  
Germany

Phone: +49 (0)69 305 35 835

E-mail: dental.eu@kuraray.com

**· Further information obtainable from: Supplier****· 1.4 Emergency telephone number:**

[United Kingdom] Only for NHS and other healthcare professionals; UK National Poisons Information Service (NPIS): +44 (0)344 892 0111 Ireland NPIC: +353 (0)1 809 2566

For members of Public; NHS 111 in England: 111, NHS 24 in Scotland: 111, NHS Direct in Wales: 111 or 0845 4647, Ireland NPIC: +353 (0)1 809 2166(8 am to 10 pm)

3E Company; (UK) 0 800 680 0425 (GB) +44 20 35147487 (AU) +61 2 80363166 \*Kuraray Access Code: 334674

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**SECTION 2: Hazards identification****· 2.1 Classification of the substance or mixture****· Classification according to Regulation (EC) No 1272/2008**

The product is not classified, according to the GB CLP regulation.

**· Additional information**

Medical devices as defined in Regulation (EU) 2017/745 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 (GB CLP/GHS) usually if they are in the finished state and intended for the final user.

**· 2.2 Label elements****· Labelling according to Regulation (EC) No 1272/2008** Void**· Hazard pictograms** Void**· Signal word** Void**· Hazard statements** Void**· Additional Information**

EUH208 Contains 2-dimethylaminoethyl methacrylate. May produce an allergic reaction.

EUH210 Safety data sheet available on request.

**· 2.3 Other hazards****· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.

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**SECTION 3: Composition/information on ingredients****· 3.2 Mixtures****· Description:** Mixture of substances listed below with nonhazardous additions.**· Dangerous components:**

CAS: 2867-47-2

2-dimethylaminoethyl methacrylate

&lt; 1%

EINECS: 220-688-8

Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317

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- **Additional information:** Aluminium oxide; Nanoform, particle size 1 - 100 nm

<b>SECTION 4: First aid measures</b>	
· <b>4.1 Description of first aid measures</b>	
· <b>After inhalation:</b> Supply fresh air; consult doctor in case of complaints.	
· <b>After skin contact:</b> Generally the product does not irritate the skin.	
· <b>After eye contact:</b> Rinse opened eye for several minutes under running water.	
· <b>After swallowing:</b> If symptoms persist consult doctor.	
· <b>4.2 Most important symptoms and effects, both acute and delayed</b>	
No further relevant information available.	
· <b>4.3 Indication of any immediate medical attention and special treatment needed</b>	
No further relevant information available.	

<b>SECTION 5: Firefighting measures</b>	
· <b>5.1 Extinguishing media</b>	
· <b>Suitable extinguishing agents:</b>	
CO <sub>2</sub> , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.	
Use fire extinguishing methods suitable to surrounding conditions.	
· <b>5.2 Special hazards arising from the substance or mixture</b>	No further relevant information available.
· <b>5.3 Advice for firefighters</b>	
· <b>Protective equipment:</b>	No special measures required.

<b>SECTION 6: Accidental release measures</b>	
· <b>6.1 Personal precautions, protective equipment and emergency procedures</b>	See Section 8.
· <b>6.2 Environmental precautions:</b>	No special measures required.
· <b>6.3 Methods and material for containment and cleaning up:</b>	
Contain spill, then place in a suitable container. Minimize dust generation. Do not flush to sewer or allow to enter waterways.	
Vacuum or sweep material and place in a disposal container. Provide ventilation.	
Use appropriate Personal Protective Equipment (PPE).	
· <b>6.4 Reference to other sections</b>	
See Section 7 for information on safe handling.	
See Section 8 for information on personal protection equipment.	
See Section 13 for disposal information.	

<b>SECTION 7: Handling and storage</b>	
· <b>7.1 Precautions for safe handling</b>	Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.
· <b>Information about fire - and explosion protection:</b>	No special measures required.
· <b>7.2 Conditions for safe storage, including any incompatibilities</b>	
· <b>Storage:</b>	
· <b>Requirements to be met by storerooms and receptacles:</b>	Store in a cool location (2-25°C).
· <b>Information about storage in one common storage facility:</b>	Not required.
· <b>Further information about storage conditions:</b>	
Keep container tightly sealed.	
Protect from heat and direct sunlight.	
Store in cool, dry conditions in well sealed receptacles.	

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- **7.3 Specific end use(s)** No further relevant information available.

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**SECTION 8: Exposure controls/personal protection****· 8.1 Control parameters****· Ingredients with limit values that require monitoring at the workplace:****1344-28-1 aluminium oxide**

WEL (Great Britain)	Long-term value: 10* 4** mg/m <sup>3</sup> *inhalable dust **respirable dust
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- **Additional information:** The lists valid during the making were used as basis.

**· 8.2 Exposure controls**

- **Appropriate engineering controls** No further data; see section 7.

**· Personal protective equipment:**

- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.

- **Respiratory protection:** Suitable respiratory protective device recommended.

**· Hand protection**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

**· Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

**· Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye/face protection** Safety glasses

**SECTION 9: Physical and chemical properties****· 9.1 Information on basic physical and chemical properties****· General Information****· Physical state**

Solid

**· Colour:**

Colored

**· Odour:**

Odourless

**· Melting point/freezing point:**

Not determined.

**· Boiling point or initial boiling point and boiling range**

Not determined.

**· Flammability**

Not determined.

**· Lower and upper explosion limit**

Not applicable.

**· Lower:**

Not applicable.

**· Upper:**

Not applicable

**· Flash point:**

Not applicable

**· Auto-ignition temperature:**

Not applicable.

**· Decomposition temperature:**

Not applicable.

**· pH**

Not determined.

**· Kinematic viscosity**

Not applicable.

**· Solubility**

Insoluble.

**· water:**

Not applicable.

**· Partition coefficient n-octanol/water (log value)**

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· <b>Vapour pressure:</b>	Not applicable.
· <b>Density at 20 °C:</b>	2.5 g/cm <sup>3</sup>
· <b>Relative vapour density</b>	Not applicable.
· <b>Particle characteristics</b>	See Section 3.
<b>· 9.2 Other information</b>	
<b>· Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Product does not present an explosion hazard.
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** No hazardous reaction when handled and stored according to provisions.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

**SECTION 11: Toxicological information**

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

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**\* SECTION 12: Ecological information**

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:** Not hazardous for water.

**SECTION 13: Disposal considerations**

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Dispose of packaging according to regulations on the disposal of packagings.

**SECTION 14: Transport information**

· <b>14.1 UN number or ID number</b>	
· ADR, ADN, IMDG, IATA	Void
· <b>14.2 UN proper shipping name</b>	
· ADR, ADN, IMDG, IATA	Void
· <b>14.3 Transport hazard class(es)</b>	
· ADR, IMDG, IATA	
· Class	Void
· <b>14.4 Packing group</b>	
· ADR, ADN, IMDG, IATA	Void
· <b>14.5 Environmental hazards:</b>	Not applicable.
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable.
· <b>UN "Model Regulation":</b>	Void

**\* SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Regulated explosives precursors**

None of the ingredients is listed.

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**· Regulated poisons**

None of the ingredients is listed.

**· Reportable explosives precursors**

None of the ingredients is listed.

**· Reportable poisons**

None of the ingredients is listed.

**· Directive 94/33/EC:** Care should be taken when people under 18 handle this product.**· Directive 94/85/EEC:** No further relevant information available.**· Named dangerous substances - ANNEX I** None of the ingredient is listed.**· Regulation (EU) No 649/2012**

None of the ingredients is listed.

**· Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

**· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

**· Regulation (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone-depleting potential)**

None of the ingredients is listed.

**· 15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

**· Relevant phrases**

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

**· Classification according to Regulation (EC) No 1272/2008**

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

**· Abbreviations and acronyms:**

ELINCS: European List of Notified Chemical Substances

Acute Tox. 4: Acute toxicity – Category 4

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

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

Skin Sens. 1: Skin sensitisation – Category 1