

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

- **1.1 Product identifier**
- **Trade name:** ESTENIA C&B ; EG FIBER
- **Article number:** 095-FB
- **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

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
Repr. 1B H360 May damage fertility or the unborn child.
- **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**  
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**  

  
 GHS07 GHS08
- **Signal word** Danger
- **Hazard-determining components of labelling:**  
Urethane dimethacrylate  
diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide  
Triethyleneglycol dimethacrylate
- **Hazard statements**  
H317 May cause an allergic skin reaction.  
H360 May damage fertility or the unborn child.
- **Precautionary statements**  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P272 Contaminated work clothing should not be allowed out of the workplace.

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- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
 P302+P352 IF ON SKIN: Wash with plenty of water.  
 P308+P313 IF exposed or concerned: Get medical advice/attention.  
 P321 Specific treatment (see on this label).  
 P362+P364 Take off contaminated clothing and wash it before reuse.  
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
 P405 Store locked up.  
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

**SECTION 3: Composition/information on ingredients**

- **3.2 Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

**· Dangerous components:**

|                                      |                                                                                             |          |
|--------------------------------------|---------------------------------------------------------------------------------------------|----------|
| CAS: 72869-86-4<br>EINECS: 276-957-5 | Urethane dimethacrylate<br>⚠ Skin Sens. 1B, H317                                            | 20 - 40% |
| CAS: 109-16-0<br>EINECS: 203-652-6   | Triethyleneglycol dimethacrylate<br>⚠ Skin Sens. 1B, H317                                   | < 5%     |
| CAS: 75980-60-8<br>EINECS: 278-355-8 | diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide<br>⚠ Repr. 1B, H360; ⚠ Skin Sens. 1B, H317 | < 1%     |

**· SVHC**

|            |                                                  |
|------------|--------------------------------------------------|
| 75980-60-8 | diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide |
|------------|--------------------------------------------------|

- **Additional information:** Silicon oxide; Nanoform, Silanated amorphous silica, particle size 1 - 100 nm

**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**  
Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

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- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** See Section 8.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to section 13.  
Ensure adequate ventilation.  
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).
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Open and handle receptacle with care.  
Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location (2-25°C).
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Protect from heat and direct sunlight.  
Store in cool, dry conditions in well sealed receptacles.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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:**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Store protective clothing separately.
- **Respiratory protection:** Suitable respiratory protective device recommended.

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**· Hand protection**


Protective gloves

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                          |                     |
| · 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                                               |                     |
| · water:                                                   | Insoluble.          |
| · Partition coefficient n-octanol/water (log value)        | Not applicable.     |
| · Vapour pressure:                                         | Not applicable.     |
| · Density at 20 °C:                                        | 2 g/cm <sup>3</sup> |
| · Relative vapour density                                  | Not applicable.     |
| · Particle characteristics                                 | See Section 3.      |

**· 9.2 Other information**
**· Information with regard to physical hazard classes**

|                        |                                               |
|------------------------|-----------------------------------------------|
| · Explosives           | Product does not present an explosion hazard. |
| · Flammable gases      | Void                                          |
| · Aerosols             | Void                                          |
| · Oxidising gases      | Void                                          |
| · Gases under pressure | Void                                          |
| · Flammable liquids    | Void                                          |

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|                                                                             |      |
|-----------------------------------------------------------------------------|------|
| · Flammable solids                                                          | Void |
| · Self-reactive substances and mixtures                                     | Void |
| · Pyrophoric liquids                                                        | Void |
| · Pyrophoric solids                                                         | Void |
| · Self-heating substances and mixtures                                      | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids                                                         | Void |
| · Oxidising solids                                                          | Void |
| · Organic peroxides                                                         | Void |
| · Corrosive to metals                                                       | Void |
| · Desensitised explosives                                                   | 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.

#### · LD/LC50 values relevant for classification:

##### 72869-86-4 Urethane dimethacrylate

|      |      |                   |
|------|------|-------------------|
| Oral | LD50 | 2,000 mg/kg (rat) |
|------|------|-------------------|

##### 109-16-0 Triethyleneglycol dimethacrylate

|      |      |                     |
|------|------|---------------------|
| Oral | LD50 | 2,000 mg/kg (mouse) |
|      |      | 10,800 mg/kg (rat)  |

- **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**  
May cause an allergic skin reaction.
- **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**  
May damage fertility or the unborn child.
- **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.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.

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- **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** For information on endocrine disrupting properties see section 11.
- **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>                                  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                         | Void            |
| · <b>14.2 UN proper shipping name</b>                                 |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                         | Void            |
| · <b>14.3 Transport hazard class(es)</b>                              |                 |
| · <b>ADR, IMDG, IATA</b>                                              |                 |
| · <b>Class</b>                                                        | Void            |
| · <b>14.4 Packing group</b>                                           |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                         | 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.

· **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.

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- **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.

|                                      |
|--------------------------------------|
| · <b>Regulation (EU) No 649/2012</b> |
|--------------------------------------|

|                                    |
|------------------------------------|
| None of the ingredients is listed. |
|------------------------------------|

|                                                         |
|---------------------------------------------------------|
| · <b>Regulation (EC) No 273/2004 on drug precursors</b> |
|---------------------------------------------------------|

|                                    |
|------------------------------------|
| None of the ingredients is listed. |
|------------------------------------|

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

|                                    |
|------------------------------------|
| None of the ingredients is listed. |
|------------------------------------|

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

|                                    |
|------------------------------------|
| None of the ingredients is listed. |
|------------------------------------|

|                                                                                          |
|------------------------------------------------------------------------------------------|
| · <b>Additional classification according to Decree on Hazardous Materials, Annex II:</b> |
|------------------------------------------------------------------------------------------|

|                                                                                |
|--------------------------------------------------------------------------------|
| · <b>Substances of very high concern (SVHC) according to REACH, Article 57</b> |
|--------------------------------------------------------------------------------|

|                                                             |
|-------------------------------------------------------------|
| 75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide |
|-------------------------------------------------------------|

- **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**

H317 May cause an allergic skin reaction.  
H360 May damage fertility or the unborn child.

- **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  
SVHC: Substances of Very High Concern  
Skin Sens. 1: Skin sensitisation – Category 1  
Skin Sens. 1B: Skin sensitisation – Category 1B  
Repr. 1B: Reproductive toxicity – Category 1B

- **\* Data compared to the previous version altered.**

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