

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

· 1.1 Product identifier

· **Trade name:** ESTENIA C&B ; BODY (Transparent, Enamel, Cervical Transparent, Transparent Effect, Enamel Effect)

· **Article number:** 095-E

· **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 crown and bridge restorative material

· 1.3 Details of the supplier of the safety data sheet

· **Manufacturer:**

Kuraray Europe GmbH
Philipp-Reis-Str. 4,
65795 Hattersheim am Main
Germany
Phone:+49 (0)69 305 35 840
Fax:+49 (0)69 305 35 640
E-mail: dental@kuraray.de

· **Supplier:**

J & S Davis
5 Whitworth Road, Stevenage,
Hertfordshir, SG1 4QS
Great Britain
Tel: +44- (0) 1438 747344
Fax: +44- (0)1438 758909
E-mail: jsdsales@js-davis.co.uk

· **Further information obtainable from:** Manufacturer or Supplier

· 1.4 Emergency telephone number:

National Poisons information Service (London Centre)
Guy's & St. Thomas' Hospital Trust
Medical Toxicology Unit
Avonley Road
LONDON
SE14 5ER
Emergency telephone: (local) 0870 600 6266 or +44 20 7771 5394
Administrative telephone: +44 20 7 771 53 10
Facsimile number: +44 20 7 771 53 09

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 CLP regulation.

· 2.2 Label elements

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

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· 2.3 Other hazards

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

Trade name: ESTENIA C&B ; BODY (Transparent, Enamel, Cervical Transparent, Transparent Effect, Enamel Effect)

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.
- **Dangerous components:** Void
- **Other ingredients:**
 - Urethane tetramethacrylate
 - Hydrophobic aromatic dimethacrylate
 - Hydrophobic aliphatic methacrylate
 - Surface treated alumina micro filler
 - Silanated glass ceramics
 - Initiators
 - Accelerators
 - Pigments

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **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.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **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:** Pick up mechanically.
- **6.4 Reference to other sections** No dangerous substances are released.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

(Contd. on page 3)

Trade name: ESTENIA C&B ; BODY (Transparent, Enamel, Cervical Transparent, Transparent Effect, Enamel Effect)

(Contd. of page 2)

- **Further information about storage conditions:**
 Keep container tightly sealed.
 Store in cool, dry conditions in well sealed receptacles.
 Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
 The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**
 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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Pasty
Colour:	Coloured
Odour:	Odourless
- **pH-value:** Not determined
- **Change in condition**

Melting point/Melting range:	Not determined
Boiling point/Boiling range:	Not determined
- **Flash point:** Not determined
- **Ignition temperature:** Not determined

(Contd. on page 4)

Trade name: ESTENIA C&B ; BODY (Transparent, Enamel, Cervical Transparent, Transparent Effect, Enamel Effect)

(Contd. of page 3)

· Decomposition temperature:	Not determined
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined
Upper:	Not determined
· Oxidising properties	Not determined
· Vapour pressure:	Not determined
· Density:	2.5 g/cm ³
· Relative density	Not determined
· Vapour density	Not determined
· Evaporation rate	Not determined
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient (n-octanol/water):	Not applicable
· Viscosity:	Not determined
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **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 toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.

(Contd. on page 5)

Trade name: ESTENIA C&B ; BODY (Transparent, Enamel, Cervical Transparent, Transparent Effect, Enamel Effect)

(Contd. of page 4)

- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 14.1 UN-Number | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | |
| · 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. |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
- **Substances of very high concern (SVHC) according to REACH, Article 57**
- **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.

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