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,
Hertfordshire, 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.
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.

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

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

- 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/cm³
- 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: 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.
  - 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.
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.

13.2 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: 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.

14.8 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.