

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 18.08.2016

Version number 6

Revision: 18.08.2016

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

- **1.1 Product identifier**
- **Trade name:** ESTENIA C&B ; OPAQUE (Body Opaque, Cervical Opaque, Opaque Modifier)
- **Article number:** 095-OP
- **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**



GHS07

Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
- **Precautionary statements**
P280 Wear protective gloves/protective clothing/eye protection/face protection.

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 18.08.2016

Version number 6

Revision: 18.08.2016

Trade name: ESTENIA C&B ; OPAQUE (Body Opaque, Cervical Opaque, Opaque Modifier)

(Contd. of page 1)

- P264 Wash thoroughly after handling.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P321 Specific treatment (see on this label).
 P332+P313 If skin irritation occurs: Get medical advice/attention.
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P302+P352 IF ON SKIN: Wash with plenty of water.
 P362+P364 Take off contaminated clothing and wash it before reuse.

- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard-determining components of labelling:** bisphenol A diglycidylmethacrylate
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.1 Chemical characterisation: Substances** None
- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 1565-94-2	bisphenol A diglycidylmethacrylate	<10%
EINECS: 216-367-7	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	

· **Other ingredients:**

Hydrophobic aromatic dimethacrylate
 Silanated glass filler
 Pre-polymerized organic filler
 Silanated titanium oxide
 Silanated barium sulfate
 Silanated colloidal silica
 dl-Camphorquinone
 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:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**
 Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **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.

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 18.08.2016

Version number 6

Revision: 18.08.2016

Trade name: ESTENIA C&B ; OPAQUE (Body Opaque, Cervical Opaque, Opaque Modifier)

(Contd. of page 2)

- **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** Not required.
- **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.
- **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:**



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**

(Contd. on page 4)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 18.08.2016

Version number 6

Revision: 18.08.2016

Trade name: ESTENIA C&B ; OPAQUE (Body Opaque, Cervical Opaque, Opaque Modifier)

(Contd. of page 3)

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:** Safety glasses

*

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Pasty
· Colour:	Coloured
· Odour:	Slightly methacrylate odour

· **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

· **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:	1.7 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 determined

· **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.

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 18.08.2016

Version number 6

Revision: 18.08.2016

Trade name: ESTENIA C&B ; OPAQUE (Body Opaque, Cervical Opaque, Opaque Modifier)

(Contd. of page 4)

 · **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**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **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.
- **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 |

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 18.08.2016

Version number 6

Revision: 18.08.2016

Trade name: ESTENIA C&B ; OPAQUE (Body Opaque, Cervical Opaque, Opaque Modifier)

(Contd. of page 5)

- | | |
|--|-----------------|
| · 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**
No further relevant information available.
- **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.

- **Relevant phrases**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
- **Abbreviations and acronyms:**
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- *** Data compared to the previous version altered.**

GB