

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

- **Product identifier**
- **Trade name:** CLEARFIL MAJESTY ES-2 ; Translucent
- **Article number:** 178-T
- **Registration number** Not applicable
- **Application of the substance / the preparation** Dental filling material
- **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  
Unit 6, Argyle Way Trading Estate,  
Fulton Close, Stevenage,  
Hertfordshire, SG 1 2AF,  
Great Britain  
Tel: +44- (0)1438 735800  
Fax: +44- (0)1438 735801  
E-mail: jsdsales@js-davis.co.uk
- **Further information obtainable from:** Manufacturer or Supplier
- **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

**2 Hazards identification**

- **Classification of the substance or mixture**
  - **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified according to the CLP regulation.
  - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
  - **Information concerning particular hazards for human and environment:**  
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
  - **Classification system:**  
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- 
- **Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008** Void
  - **Hazard pictograms** Void
  - **Signal word** Void
  - **Hazard statements**  
Safety data sheet available on request.
  - **Other hazards**
  - **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.

## Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.10.2012

Revision: 21.09.2012

**Trade name:** CLEARFIL MAJESTY ES-2 ; Translucent



· **vPvB:** Not applicable.

(Contd. of page 1)

### 3 Composition/information on ingredients

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

· **Dangerous components:**

CAS: 1565-94-2	bisphenol A diglycidylmethacrylate	<10%
EINECS: 216-367-7	 Xi R36/38  Skin Irrit. 2, H315; Eye Irrit. 2, H319	

· **Other ingredients:**

Silanated barium glass filler  
 Hydrophobic aromatic dimethacrylate  
 Hydrophobic aliphatic dimethacrylate  
 dl-Camphorquinone  
 Accelerators  
 Initiators  
 Pigments

### 4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **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. If symptoms persist, consult a doctor.
- **After swallowing:**  
 Do not induce vomiting; call for medical help immediately.  
 If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
 No further relevant information available.

### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
 CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**  
 No dangerous substances are released.

(Contd. on page 3)

**Trade name: CLEARFIL MAJESTY ES-2 ; Translucent**

(Contd. of page 2)

See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **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.
- **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.
- **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.

GB

(Contd. on page 4)

**Trade name: CLEARFIL MAJESTY ES-2 ; Translucent**

(Contd. of page 3)

## 9 Physical and chemical properties

· <b>Information on basic physical and chemical properties</b>	
· <b>General Information</b>	
· <b>Appearance:</b>	
· <b>Form:</b>	Pasty
· <b>Colour:</b>	Different according to colouring
· <b>Odour:</b>	Odourless
· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not applicable
· <b>Change in condition</b>	
· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Ignition temperature:</b>	Not applicable
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
· <b>Lower:</b>	Not applicable
· <b>Upper:</b>	Not applicable
· <b>Vapour pressure:</b>	Not applicable
· <b>Density at 20°C:</b>	2.1 g/cm <sup>3</sup>
· <b>Vapour density</b>	Not applicable
· <b>Solubility in / Miscibility with water:</b>	
	Insoluble.
· <b>Segregation coefficient (n-octanol/water):</b> Not applicable	
· <b>VOC (EC)</b>	0.00 %
· <b>Other information</b>	No further relevant information available.

## 10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

## 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

(Contd. on page 5)

**Trade name: CLEARFIL MAJESTY ES-2 ; Translucent**

(Contd. of page 4)

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

**12 Ecological information**

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

**13 Disposal considerations**

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

**14 Transport information**

· <b>UN-Number</b>	
· <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>UN proper shipping name</b>	
· <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>Transport hazard class(es)</b>	
· <b>ADR, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>Packing group</b>	
· <b>ADR, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	-

GB

(Contd. on page 6)

Printing date 17.10.2012

Revision: 21.09.2012

**Trade name: CLEARFIL MAJESTY ES-2 ; Translucent**

(Contd. of page 5)

**15 Regulatory information**

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**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.

- **Version:** 1

- **Relevant phrases**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

R36/38 Irritating to eyes and skin.

GB