

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

· 1.1 Product identifier

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

· **Article number:** 178-T

· **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 filling 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.

Trade name: CLEARFIL MAJESTY ES-2 ; Translucent

(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:**

CAS: 1565-94-2	bisphenol A diglycidylmethacrylate	<10%
EINECS: 216-367-7	⚠ 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

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **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.

· **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:** Do not allow to enter sewers/ surface or ground water.

· **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.

· **6.4 Reference to other sections**

No dangerous substances are released.

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

(Contd. on page 3)

Trade name: CLEARFIL MAJESTY ES-2 ; Translucent

See Section 13 for disposal information.

(Contd. of page 2)

SECTION 7: Handling and storage

- **7.1 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.
- **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:**
 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:** Goggles recommended during refilling

GB

(Contd. on page 4)

Trade name: CLEARFIL MAJESTY ES-2 ; Translucent

(Contd. of page 3)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

· **Form:** Pasty
· **Colour:** Different according to colouring

· **Odour:** Odourless

· **Odour threshold:** Not determined

· **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 at 20 °C:** 2.1 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

· **VOC (EC):** 0.00 %

· **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.

(Contd. on page 5)

Trade name: CLEARFIL MAJESTY ES-2 ; Translucent

(Contd. of page 4)

- **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:**
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.
- **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. |

(Contd. on page 6)

Printing date 12.10.2016

Version number 2

Revision: 12.10.2016

Trade name: CLEARFIL MAJESTY ES-2 ; Translucent

(Contd. of page 5)

· 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