


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

- **1.1 Product identifier**
- **Trade name:** CLEARFIL MAJESTY ES-2
- **Article number:** 178
- **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**
- **Supplier :**
Kuraray Europe GmbH
Philipp-Reis-Str. 4,
65795 Hattersheim am Main
Germany
Phone: +49 (0)69 305 35 835
E-mail: dental.eu@kuraray.com
- **Further information obtainable from:** Supplier
- **1.4 Emergency telephone number:**
(UK) 0 800 680 0425
(GB) +44 20 35147487
(AU) +61 2 80363166
* 3E Company
* Kuraray Access Code:334674

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Regulation (EC) No 1272/2008**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
 - **Additional information :**
Medical devices as defined in Regulation (EU) 2017/745 and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (GB CLP/ GHS) usually if they are in the finished state and intended for the final user.
 - **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
 - **Hazard pictograms**
- 

GHS07
- **Signal word** Warning
 - **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
 - **Precautionary statements**
- | | |
|----------------|--|
| P264 | Wash thoroughly after handling. |
| P280 | Wear protective gloves / eye protection / face protection. |
| P302+P352 | IF ON SKIN: Wash with plenty of water. |
| P321 | Specific treatment (see on this label). |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P332+P313 | If skin irritation occurs: Get medical advice/attention. |

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Trade name: CLEARFIL MAJESTY ES-2

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P362+P364 Take off contaminated clothing and wash it before reuse.
P337+P313 If eye irritation persists: Get medical advice/attention.

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

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

· **Dangerous components:**

CAS: 1565-94-2	bisphenol A diglycidylmethacrylate	5-15%
EINECS: 216-367-7	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	
CAS: 75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide	<1%
EINECS: 278-355-8	⚠ Repr. 2, H361f	

· **Other ingredients:**

Silanated barium glass filler
Pre-polymerized organic filler
Hydrophobic aromatic dimethacrylate
Silanated amorphous silica
Hydrophobic aliphatic dimethacrylate

Accelerator

dl-Camphorquinone

Pigments

· **Additional information:**

Silicon oxide; Nanoform, Pre-polymerized organic filler and Silanated amorphous silica, particle size 1 - 100 nm

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.
- **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.

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Trade name: CLEARFIL MAJESTY ES-2

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- **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. Ensure adequate ventilation.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **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

- **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**
- **Appropriate engineering controls** No further data; see item 7.
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Hand protection**



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**

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.

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Trade name: CLEARFIL MAJESTY ES-2

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· Eye/face protection



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state	Solid
· Colour:	Different according to colouring
· Odour:	Odourless
· Odour threshold:	Not determined
· Melting point/freezing point:	Not determined
· Boiling point or initial boiling point and boiling range	Not determined
· Flammability	Not determined.
· Lower and upper explosion limit	
· Lower:	Not determined
· Upper:	Not determined
· Flash point:	Not determined
· Auto-ignition temperature:	Not determined
· Decomposition temperature:	Not determined
· pH	Not determined
· Viscosity:	Not determined
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined
· Vapour pressure:	Not determined
· Density and/or relative density	
· Density at 20 °C:	1.8 - 2.1 g/cm ³
· Relative density	Not determined
· Relative vapour density	Not determined
· Particle characteristics	See item 3.

· 9.2 Other information

· Appearance:	
· Form:	Pasty
· Important information on protection of health and environment, and on safety.	
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Softening point/range	
· Oxidising properties	Not determined
· Evaporation rate	Not determined
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void

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Trade name: CLEARFIL MAJESTY ES-2

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· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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.
- **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.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

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Trade name: CLEARFIL MAJESTY ES-2

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Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN number or ID 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 Maritime transport in bulk according to IMO instruments | 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.
- **Directive 94/33/EC:** Care should be taken when people under 18 handle this product.
- **Directive 94/85/EEC:** No further relevant information available.
- **Chemical safety assessment**
- **Named dangerous substances - ANNEX I** None of the ingredient is listed.
- **Regulation (EU) No 649/2012**

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

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

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Trade name: CLEARFIL MAJESTY ES-2

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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.

H361f Suspected of damaging fertility.

· Abbreviations and acronyms:

ELINCS: European List of Notified Chemical Substances

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Repr. 2: Reproductive toxicity – Category 2

· * Data compared to the previous version altered.

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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 35835
Fax: +49 (0) 69 305 9835835
E-mail: dental.eu@kuraray.com
- **Further information obtainable from:** Manufacturer
- **1.4 Emergency telephone number:**

(UK) 0 800 680 0425
(GB) +44 20 35147487
(AU) +61 2 80363166
* Verisk 3E
* Kuraray Access Code: 334674

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.

GB

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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.

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Trade name: CLEARFIL MAJESTY ES-2 ; Translucent

See Section 13 for disposal information.

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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 through 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

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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.

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

Printing date 01.08.2020

Version number 3

Revision: 01.08.2020

Trade name: CLEARFIL MAJESTY ES-2 ; Translucent

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- **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.

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Trade name: CLEARFIL MAJESTY ES-2 ; Translucent

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· 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.**

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

- **1.1 Product identifier**
- **Trade name:** CLEARAFIL MAJESTY ES-2; Classic, Premium and Universal
- **Article number:** 178-CP
- **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 35835
Fax: +49 (0)69 305 98 35835
E-mail: dental.eu@kuraray.com
- **Further information obtainable from:** Manufacturer
- **1.4 Emergency telephone number:**
(UK) 0 800 680 0425
(GB) +44 20 35147487
(AU) +61 2 80363166
* 3E Company
* Kuraray Access Code:334674

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
- **Additional information:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.
- **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**
P264 Wash hands thoroughly after handling.
P280 Wear protective gloves / eye protection / face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P321 Specific treatment (see on this label).
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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Trade name: CLEARFIL MAJESTY ES-2; Classic, Premium and Universal

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- P332+P313 If skin irritation occurs: Get medical advice/attention.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P337+P313 If eye irritation persists: Get medical advice/attention.

- **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

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

- **Dangerous components:**

CAS: 1565-94-2	bisphenol A diglycidylmethacrylate	5-15%
EINECS: 216-367-7	 Skin Irrit. 2, H315; Eye Irrit. 2, H319	

- **Other ingredients:**

- Silanated barium glass filler
- Pre-polymerized organic 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; 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.
- **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:** Do not allow to enter sewers/ surface or ground water.

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- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **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:** Wash hands before breaks and at the end of work.
- **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**

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.

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· **Eye protection:**



Tightly sealed goggles

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/freezing point:	Not determined
· Initial boiling point and boiling range:	Not determined

· **Flash point:** Not determined

· **Ignition temperature:** Not determined

· **Decomposition temperature:** Not determined

· **Explosive properties:** 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:** 1.8 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 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.

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· **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:**
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**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **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 |

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· 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**
No further relevant information available.
- **Directive 94/33/EC:** Care should be taken when people under 18 handle this product.
- **Directive 94/85/EEC:** No further relevant information available.
- **Named dangerous substances - ANNEX I** None of the ingredient is listed.
- **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.

- **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.**