

SAFETY DATA SHEETS

This SDS packet was issued with item:

074577441

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

074577334 074577342 074577359 074577367 074577375 074577383 074577391 074577409 074577417 074577425

074577433 074577458 074577466 074577474

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/20/2020

Version 3

Reviewed on 11/20/2020

1 Identification

- **Product identifier**
- **Trade name:** CLEARFIL MAJESTY ES-2; Classic, Premium and Universal
- **Article number:** US178-CP
- **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
- **Details of the supplier of the safety data sheet**
- **Manufacturer:**
Kuraray Noritake Dental Inc.
1621 Sakazu, Kurashiki, Okayama 710-0801,
Japan
- **Contact information:**
Kuraray America, Inc.
32 Old Slip, 7th Floor, New York,
NY 10005 U.S.A.
Tel: 800-879-1676
Fax: 888-700-5200
Website: www.kuraraydental.com
- **Emergency telephone number:**
For chemical emergency spill, leak, fire, exposure or accident
Call CHEMTREC day and night
Within USA and Canada: 1-800-424-9300 CCN706984 or
+1 703-527-3887 (collect calls accepted)

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS07

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

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **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.
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.
P362+P364 Take off contaminated clothing and wash it before reuse.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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

· vPvB: Not applicable.

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3 Composition/information on ingredients

· **Chemical characterization: Mixtures**· **Description:** Mixture of substances listed below with nonhazardous additions.· **Dangerous components:**

1565-94-2 bisphenol A diglycidylmethacrylate



Skin Irrit. 2, H315; Eye Irrit. 2A, H319

5-15%

· **Other ingredients:**

Silanated barium glass filler

Pre-polymerized organic filler

Hydrophobic aromatic dimethacrylate

Hydrophobic aliphatic dimethacrylate

dl-Camphorquinone

Accelerators

Initiators

Pigments

4 First-aid measures

· **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.

If skin irritation continues, consult a doctor.

· **After eye contact:** Rinse opened eye for several minutes under running water.· **After swallowing:** 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 Fire-fighting measures

· **Extinguishing media**· **Suitable extinguishing agents:**CO₂, extinguishing 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** See Section 8.· **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**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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

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· Protective Action Criteria for Chemicals**· PAC-1:**

None of the ingredients is listed.

· PAC-2:

None of the ingredients is listed.

· PAC-3:

None of the ingredients is listed.

7 Handling and storage**· Handling:****· Precautions for safe handling** No special precautions are necessary if used correctly.**· Information about protection against explosions and fires:** 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 receptacle 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 systems:** No further data; see item 7.**· Control parameters****· Components 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 that were valid during the creation were used as basis.**· Exposure controls****· Personal protective equipment:****· General protective and hygienic measures:** Wash hands before breaks and at the end of work.**· Breathing equipment:** 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.

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

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· **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:**

Tightly sealed goggles

9 Physical and chemical properties· **Information on basic physical and chemical properties**· **General Information**· **Appearance:****Form:**

Pasty

Color:

Different according to coloring

· **Odor:**

Odorless

· **Odor 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.

· **Oxidizing properties**

Not determined

· **Vapor pressure:**

Not determined

· **Density at 20 °C:**1.8 g/cm³· **Relative density**

Not determined

· **Vapor density**

Not determined

· **Evaporation rate**

Not determined

· **Solubility in / Miscibility with****Water:**

Insoluble.

· **Partition coefficient (n-octanol/water):**

Not determined

· **Viscosity:**

Not determined

· **Other information**

No further relevant information available.

10 Stability and reactivity· **Reactivity** No further relevant information available.· **Chemical stability**· **Thermal decomposition / conditions to be avoided:**

No decomposition if used and stored according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known.

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

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- **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:** Irritating effect
- **on the eye:** Irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product is not subject to classification according to internally approved calculation methods for preparations:
- **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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 (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:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Void

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

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

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
No further relevant information available.

- Sara

- Section 355 (extremely hazardous substances):

None of the ingredient is listed.

- Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

- TSCA (Toxic Substances Control Act):

All ingredients are listed.

- Proposition 65

- Chemicals known to cause cancer:

None of the ingredients is listed.

- Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

- Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

- Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

- Cancerogenity categories

- EPA (Environmental Protection Agency)

None of the ingredients is listed.

- TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

- NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

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

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

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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.

· NFPA ratings (scale 0 - 4)

Health = 1

Fire = 0

Reactivity = 0

· HMIS-ratings (scale 0 - 4)

Health = 1

Fire = 0

Reactivity = 0

· Abbreviations and acronyms:

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

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

· * Data compared to the previous version altered.

US

Printing date 10/17/2012

Reviewed on 09/13/2012

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

- **Product identifier**
- **Trade name:** CLEARFIL MAJESTY ES-2 ; Classic and Premium
- **Article number:** US178-CP
- **Application of the substance / the preparation** Dental filling material
- **Details of the supplier of the safety data sheet**
- **Manufacturer:**
Kuraray Noritake Dental Inc.
1621 Sakazu, Kurashiki, Okayama 710-0801,
Japan
- **Contact information:**
Kuraray America, Inc.
33 Maiden Lane, 6th Floor, New York,
NY 10038 U.S.A.
Tel: 800-879-1676
Fax: 888-700-5200
Website: www.kuraraydental.com

2 Composition/information on ingredients

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

· **Dangerous components:**

1565-94-2	bisphenol A diglycidylmethacrylate	 H315; H319	2.5-10%
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· **Other ingredients:**

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

3 Hazards identification

- **Classification of the substance or mixture**



GHS07

H315 Causes skin irritation.

H319 Causes serious eye irritation.

· **Label elements**· **GHS label elements**

The product is classified and labelled according to the Globally Harmonized System (GHS).

· **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.

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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USA

Printing date 10/17/2012

Reviewed on 09/13/2012

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

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- P321 Specific treatment (see on this label).
P362 Take off contaminated clothing and wash before reuse.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.

- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**
- | | | |
|------------|---|----------------|
| HEALTH | 0 | Health = 0 |
| FIRE | 0 | Fire = 0 |
| REACTIVITY | 0 | Reactivity = 0 |

4 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.

5 Firefighting measures

- **Suitable extinguishing agents:** CO₂, extinguishing 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.
- **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**
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** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** No special measures required.
- **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:** None.
- **Specific end use(s)** No further relevant information available.

USA

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Printing date 10/17/2012

Reviewed on 09/13/2012

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

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8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Components 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 that were valid during the creation were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Breathing equipment:** 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:** Not required.

9 Physical and chemical properties

- | | |
|---|---|
| · General Information | |
| · Appearance: | |
| Form: | Pasty |
| Color: | Different according to coloring |
| · Odor: | Odorless |
| · Odour threshold: | Not determined. |
| · pH-value: | Not applicable |
| · Change in condition | |
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | Undetermined. |
| · Flash point: | Not applicable. |
| · Ignition temperature: | Not applicable |
| · Danger of explosion: | Product does not present an explosion hazard. |
| · Explosion limits: | |
| Lower: | Not applicable |
| Upper: | Not applicable |
| · Vapor pressure: | Not applicable |
| · Density at 20°C (68 °F): | 1.8 g/cm ³ (15.021 lbs/gal) |
| · Vapour density | Not applicable |
| · Solubility in / Miscibility with Water: | Insoluble. |
| · Segregation coefficient (n-octanol/water): | Not applicable |

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USA

Printing date 10/17/2012

Reviewed on 09/13/2012

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

(Contd. of page 3)

· Other information

No further relevant information available.

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

11 Toxicological information

- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.

12 Ecological information

- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (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.

13 Disposal considerations

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

14 Transport information

- | | |
|--------------------------------|-----------------|
| · UN-Number | Not applicable |
| · UN proper shipping name | Not applicable |
| · ADR | Void |
| · Transport hazard class(es) | Not applicable |
| · Packing group | Not applicable |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |

(Contd. on page 5)

USA

Printing date 10/17/2012

Reviewed on 09/13/2012

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

(Contd. of page 4)

- | | |
|---|-----------------|
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

15 Regulatory information

· Sara

· Section 355 (extremely hazardous substances):

None of the ingredient is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

All ingredients are listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Cancerogenity categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

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

USA