


1 Identification of substance

- **Product details**
- **Trade name:** CLEARFIL MAJESTY Esthetic, CLEARFIL MAJESTY Esthetic PLT
- **Article number:** US126
- **Application of the substance / the preparation** Dental filling material
- **Manufacturer:**
Kuraray Medical Inc.
1621 Sakazu, Kurashiki, Okayama 710-0801,
Japan
- **Supplier:**
Kuraray America, Inc.
600 Lexington Avenue, 26th Floor, New York,
NY 10022 U.S.A.
Tel: 800-879-1676
Fax: 888-700-5200
Website: www.kuraraydental.com
- **Information department:** Supplier

2 Composition/Data on components

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

- **Dangerous components:**

1565-94-2	bisphenol A diglycidylmethacrylate	Warning:  3.2/2, 3.3/2A	<15%
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- **Other ingredients:**

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

3 Hazards identification

- **Hazard description:** Not applicable.
- **Information pertaining to particular dangers for man and environment:**
The product does not have to be labelled due to the calculation procedure of international guidelines.
- **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- **NFPA ratings (scale 0 - 4)**
Health = 0
Fire = 0
Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**
Health = 0
Fire = 0
Reactivity = 0
- **GHS label elements**

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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 Fire fighting measures

- **Suitable extinguishing agents:** CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Person-related safety precautions:** Not required.
- **Measures for environmental protection:** No special measures required.
- **Measures for cleaning/collecting:** Pick up mechanically.
- **Additional information:** No dangerous substances are released.

7 Handling and storage

- **Handling:**
- **Information for safe handling:** No special measures required.
- **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.

8 Exposure controls and 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:**
The usual precautionary measures for handling chemicals should be followed.
- **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.

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- **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.

9 Physical and chemical properties

· General Information

Form:	Pasty
Color:	Colored
Odor:	Odorless

· 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:	1.9 g/cm ³
· Vapour density	Not applicable

· Solubility in / Miscibility with

Water:	Insoluble.
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· **pH-value:** Not applicable

· **Segregation coefficient (n-octanol/water):** Not applicable

10 Stability and reactivity

· Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to specifications.

· **Dangerous reactions** No dangerous reactions known.

· **Dangerous products of decomposition:** 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.

· Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

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

12 Ecological information

· **General notes:** Generally not hazardous for water

13 Disposal considerations

- **Product:**
- **Recommendation:** Smaller quantities can be disposed of with household waste.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **DOT regulations:**
- **Hazard class:** -
- **Land transport ADR/RID (cross-border):**
- **ADR/RID class:** -
- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -
- **UN "Model Regulation":** -

15 Regulations

- **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):**
None of the ingredients is 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.

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· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

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.

· **Product related hazard informations:**

Observe the general safety regulations when handling chemicals.

The product is not subject to identification regulations according to directives on hazardous materials.

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: 2**

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises Dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement internationale concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

ACGIH: American Conference of Governmental Industrial Hygienists

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)