

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

- **Product identifier**
- **Trade name:** CLEARFIL SE BOND ; PRIMER
- **Article number:** US064-P
- **Application of the substance / the preparation** Dental bonding material
- **Details of the supplier of the safety data sheet**
- **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

2 Composition/information on ingredients

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

· **Dangerous components:**

868-77-9	2-hydroxyethyl methacrylate	H315; H319; H317	10-30%
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- **Other ingredients:**
10-Methacryloyloxydecyl dihydrogen phosphate
Hydrophilic aliphatic dimethacrylate
dl-Camphorquinone
Water
Accelerators
Dyes
Others

3 Hazards identification

- **Classification of the substance or mixture**



GHS07

- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H317 May cause an allergic skin reaction.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Irritant

Irritating to eyes and skin. May cause sensitisation by skin contact.

- **Information concerning particular hazards for human and environment:**

The product has 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.

- **Label elements**

- **GHS label elements**

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

- **Hazard pictograms** GHS07

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- **Signal word** Warning
- **Hazard-determining components of labelling:**
2-hydroxyethyl methacrylate
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
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.
P321 Specific treatment (see on this label).
P362 Take off contaminated clothing and wash before reuse.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**
- | | | |
|------------|---|----------------|
| HEALTH | 1 | Health = 1 |
| FIRE | 1 | Fire = 1 |
| REACTIVITY | 0 | Reactivity = 0 |

4 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; immediately call for medical help.
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.
- **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:**
Dilute with plenty of water.

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- Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a refrigerator (2-8°C).
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.

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:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **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.
- **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.

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· **Eye protection:**



Tightly sealed goggles

9 Physical and chemical properties

· **General Information**

· **Appearance:**

· **Form:** Liquid
· **Color:** Yellow
· **Odor:** Odorless

· **pH-value at 20°C (68 °F):** 2

· **Change in condition**

· **Melting point/Melting range:** -12 °C (2-hydroxyethyl methacrylate)
· **Boiling point/Boiling range:** 205°C(2-hydroxyethyl methacrylate)

· **Flash point:** 97 °C (2-hydroxyethyl methacrylate)

· **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 g/cm³ (8.345 lbs/gal)

· **Vapour density** Not applicable

· **Solubility in / Miscibility with**

· **Water:** Fully miscible.

· **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.

· **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

11 Toxicological information

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

868-77-9 2-hydroxyethyl methacrylate

Oral	LD50	4680 mg/kg (guinea pig)
		3275 mg/kg (mouse)
		5050 mg/kg (rat)

· **Primary irritant effect:**

· **on the skin:** Irritant to skin and mucous membranes.

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- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

12 Ecological information

- **Acquatic toxicity:** 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.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

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 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.

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· **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.

· **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.

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: 3**

· **Relevant phrases**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.