

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

- **Product identifier**
- **Trade name:** CLEARFIL SE BOND ; PRIMER
- **Article number:** 064-P
- **Registration number** Not applicable
- **Application of the substance / the preparation** Dental bonding material
- **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  
Unit 6, Argyle Way Trading Estate,  
Fulton Close, Stevenage,  
Hertfordshire, SG 1 2AF,  
Great Britain  
Tel: +44- (0)1438 735800  
Fax: +44- (0)1438 735801  
E-mail: jsdsales@js-davis.co.uk
- **Further information obtainable from:** Manufacturer or Supplier
- **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

**2 Hazards identification**

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
  -  GHS05 corrosion  
Skin Corr. 1C H314 Causes severe skin burns and eye damage.
  -  GHS07  
Eye Irrit. 2 H319 Causes serious eye irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
  -  Xi; Irritant  
R36/38: Irritating to eyes and skin.
  -  Xi; Sensitising  
R43: May cause sensitisation by skin contact.

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

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

- **Classification system:**

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **Label elements**

- **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

- **Hazard pictograms** GHS05, GHS07

- **Signal word** Danger

- **Hazard-determining components of labelling:**

2-hydroxyethyl methacrylate

- **Hazard statements**

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

- **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.

P321 Specific treatment (see on this label).

P362 Take off contaminated clothing and wash before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P405 Store locked up.

- **Other hazards**

- **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

## 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

|                   |                                                             |        |
|-------------------|-------------------------------------------------------------|--------|
| CAS: 868-77-9     | 2-hydroxyethyl methacrylate                                 | 10-30% |
| EINECS: 212-782-2 | Xi R36/38; Xi R43                                           |        |
|                   | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 |        |

- **Other ingredients:**

10-Methacryloyloxydecyl dihydrogen phosphate

Hydrophilic aliphatic dimethacrylate

dl-Camphorquinone

Water

Accelerators

Dyes

Others

## 4 First aid measures

- **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.

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- **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.
- **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 Firefighting measures**

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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:**  
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.  
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 fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **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 container tightly sealed.
- **Specific end use(s)** No further relevant information available.

**8 Exposure controls/personal protection**

- **Additional information about design of technical facilities:** No further data; see item 7.

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- **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.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **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 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:   | Liquid    |
| Colour: | Yellow    |
| Odour:  | Odourless |
- **pH-value at 20°C:** 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

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|                                                     |                                               |
|-----------------------------------------------------|-----------------------------------------------|
| · <b>Danger of explosion:</b>                       | Product does not present an explosion hazard. |
| · <b>Explosion limits:</b>                          |                                               |
| Lower:                                              | Not applicable                                |
| Upper:                                              | Not applicable                                |
| · <b>Vapour pressure:</b>                           | Not applicable                                |
| · <b>Density at 20°C:</b>                           | 1 g/cm <sup>3</sup>                           |
| · <b>Vapour density</b>                             | Not applicable                                |
| · <b>Solubility in / Miscibility with water:</b>    | Fully miscible.                               |
| · <b>Segregation coefficient (n-octanol/water):</b> | Not applicable                                |
| · <b>Other information</b>                          | No further relevant information available.    |

## 10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **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:**

### · LD/LC50 values 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.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:  
Irritant

## 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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- **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.
- **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 together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

## 14 Transport information

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

## 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Labelling according to Regulation (EC) No 1272/2008 GHS label elements**
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 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:** 5

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**· Relevant phrases**

Not applicable

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

.....

R36/38 Irritating to eyes and skin.

R43 May cause sensitisation by skin contact.

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