

## 1 Identification of the substance/preparation and of the company/undertaking

• **Product details**

• **Trade name:** CLEARFIL SE BOND ; BOND

• **Article number:** 064-B

• **Application of the substance / the preparation** Dental bonding material

• **Manufacturer:**

Kuraray Europe GmbH  
Building F821, Hoechst Industrial Park  
65926 Frankfurt am Main  
Germany  
Tel: +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

• **Information in case of emergency:**

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

• **Hazard description:**



Xi Irritant

• **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.

R 36/38 Irritating to eyes and skin.

R 43 May cause sensitisation by skin contact.

• **Classification system:**

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

• **GHS label elements**



Warning

H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

H317 - May cause an allergic skin reaction.

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**Prevention:**

- P264 Wash thoroughly after handling.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.

**Response:**

- P302+P352 IF ON SKIN: Wash with plenty of soap and 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).
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P362 Take off contaminated clothing and wash before reuse.

### 3 Composition/information on ingredients

**Chemical characterization**

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

**Dangerous components:**

CAS: 1565-94-2 EINECS: 216-367-7	bisphenol A diglycidylmethacrylate Xi; R 36/38 Warning: 3.2/2, 3.3/2	25-45%
CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate Xi; R 36/38-43 Warning: 3.2/2, 3.3/2, 3.4.S/1	20-40%

**Other ingredients:**

10-Methacryloyloxydecyl dihydrogen phosphate  
Hydrophobic aliphatic dimethacrylate  
Colloidal silica  
dl-Camphorquinone  
Initiators  
Accelerators  
Others

### 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; call for medical help immediately.  
If symptoms persist consult doctor.

### 5 Fire-fighting measures

**Suitable extinguishing agents:**

CO2, 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.

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## 6 Accidental release measures

- **Person-related safety precautions:** Not required.
- **Measures for environmental protection:** Do not allow to enter sewers/ surface or ground water.
- **Measures for cleaning/collecting:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Ensure adequate ventilation.

## 7 Handling and storage

- **Handling:**
- **Information for safe handling:**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** 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 container tightly sealed.

## 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.
- **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:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **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

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## 9 Physical and chemical properties

### · General Information

<b>Form:</b>	Liquid
<b>Colour:</b>	Yellow
<b>Odour:</b>	Odourless

### · Change in condition

<b>Melting point/Melting range:</b>	-12 °C (2-hydroxyethyl methacrylate)
<b>Boiling point/Boiling range:</b>	205 °C (2-hydroxyethyl methacrylate)

<b>Flash point:</b>	97 °C (2-hydroxyethyl methacrylate)
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<b>Ignition temperature:</b>	Not applicable
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<b>Danger of explosion:</b>	Product does not present an explosion hazard.
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### · Explosion limits:

<b>Lower:</b>	Not applicable
<b>Upper:</b>	Not applicable

<b>Vapour pressure:</b>	Not applicable
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<b>Density:</b>	1.1 g/cm <sup>3</sup>
<b>Vapour density</b>	Not applicable

### · Solubility in / Miscibility with water:

Not miscible or difficult to mix.

<b>pH-value:</b>	Not applicable
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<b>Segregation coefficient (n-octanol/water):</b>	Not applicable
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## 10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Dangerous reactions** No dangerous reactions known.
- **Dangerous decomposition products:** Carbon monoxide and carbon dioxide

## 11 Toxicological information

### · 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:

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Irritant

• **Sensitisation** May cause sensitisation by skin contact.

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## 12 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.

## 13 Disposal considerations

• **Product:**

• **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.

## 14 Transport information

• **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

• **Labelling according to EU guidelines:**

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.

• **Code letter and hazard designation of product:**



Xi Irritant

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

2-hydroxyethyl methacrylate

bisphenol A diglycidylmethacrylate

• **Risk phrases:**

36/38 Irritating to eyes and skin.

43 May cause sensitisation by skin contact.

• **Safety phrases:**

24 Avoid contact with skin.

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

28 After contact with skin, wash immediately with plenty of soap and water.

37 Wear suitable gloves.

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60 This material and its container must be disposed of as hazardous waste.

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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.

· **Version: 4**

· **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 international 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

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)

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

GB

## 1 Identification of the substance/preparation and of the company/undertaking

- **Product details**
- **Trade name:** CLEARFIL SE BOND ; PRIMER
- **Article number:** 064-P
- **Application of the substance / the preparation** Dental bonding material
- **Manufacturer:**  
Kuraray Europe GmbH  
Building F821, Hoechst Industrial Park  
65926 Frankfurt am Main  
Germany  
Tel: +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
- **Information in case of emergency:**  
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

- **Hazard description:**



Xi Irritant

- **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.  
R 36/38 Irritating to eyes and skin.  
R 43 May cause sensitisation by skin contact.
- **Classification system:**  
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **GHS label elements**



Warning

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

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**Trade name: CLEARFIL SE BOND ; PRIMER**

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• **Prevention:**

P264 Wash thoroughly after handling.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.

• **Response:**

P302+P352 IF ON SKIN: Wash with plenty of soap and 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).  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P337+P313 If eye irritation persists: Get medical advice/attention.  
P362 Take off contaminated clothing and wash before reuse.

### 3 Composition/information on ingredients

• **Chemical characterization**

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

• **Dangerous components:**

CAS: 868-77-9	2-hydroxyethyl methacrylate	Xi; R 36/38-43	10-30%
EINECS: 212-782-2		Warning: 3.2/2, 3.3/2, 3.4.S/1	

• **Other ingredients:**

10-Methacryloyloxydecyl dihydrogen phosphate  
Hydrophilic aliphatic dimethacrylate  
dl-Camphorquinone  
Water  
Accelerators  
Dyes  
Others

### 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; call for medical help immediately.  
If symptoms persist consult doctor.

### 5 Fire-fighting measures

• **Suitable extinguishing agents:**

CO<sub>2</sub>, 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

• **Person-related safety precautions:** Not required.

• **Measures for environmental protection:**

Dilute with plenty of water.

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**Trade name: CLEARFIL SE BOND ; PRIMER**

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Do not allow to enter sewers/ surface or ground water.

· **Measures for cleaning/collecting:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

## 7 Handling and storage

· **Handling:**

· **Information for safe handling:**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

· **Information about fire - and explosion protection:** 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 container tightly sealed.

## 8 Exposure controls/personal protection

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

· **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.

· **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 trough 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

· **General Information**

**Form:**

Liquid

**Colour:**

Yellow

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**Trade name: CLEARFIL SE BOND ; PRIMER**

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<b>Odour:</b>	Odourless
· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	-12 °C (2-hydroxyethyl methacrylate)
<b>Boiling point/Boiling range:</b>	205 °C (2-hydroxyethyl methacrylate)
· <b>Flash point:</b>	97 °C (2-hydroxyethyl methacrylate)
· <b>Ignition temperature:</b>	Not applicable
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not applicable
<b>Upper:</b>	Not applicable
· <b>Vapour pressure:</b>	Not applicable
· <b>Density:</b>	1.0 g/cm <sup>3</sup>
· <b>Vapour density</b>	Not applicable
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>pH-value:</b>	2
· <b>Segregation coefficient (n-octanol/water):</b>	Not applicable

## 10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Dangerous reactions** No dangerous reactions known.
- **Dangerous decomposition products:** Carbon monoxide and carbon dioxide

## 11 Toxicological information

- **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
- **Sensitisation** May cause sensitisation by skin contact.

## 12 Ecological information

- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

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**Trade name: CLEARFIL SE BOND ; PRIMER**

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


### 13 Disposal considerations

- **Product:**
- **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

- **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

- **Labelling according to EU guidelines:**  
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.
- **Code letter and hazard designation of product:**  
 Xi Irritant
- **Hazard-determining components of labelling:**  
2-hydroxyethyl methacrylate
- **Risk phrases:**  
36/38 Irritating to eyes and skin.  
43 May cause sensitisation by skin contact.
- **Safety phrases:**  
24 Avoid contact with skin.  
26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
28 After contact with skin, wash immediately with plenty of soap and water.  
37 Wear suitable gloves.  
60 This material and its container must be disposed of as hazardous waste.

### 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.

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**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 international 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  
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)  
GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent

GB