


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

- **1.1 Product identifier**
- **Trade name:** CLEARFIL SE BOND ; PRIMER
- **Article number:** 064-P
- **Registration number** Not applicable
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Dental materials
- **1.3 Details of the supplier of the safety data sheet**
- **Supplier :**
Kuraray Europe GmbH
Philipp-Reis-Str. 4,
65795 Hattersheim am Main
Germany
Phone: +49 (0)69 305 35 835
E-mail: dental.eu@kuraray.com
- **Further information obtainable from:** Supplier
- **1.4 Emergency telephone number:**
[United Kingdom] Only for NHS and other healthcare professionals; UK National Poisons Information Service (NPIS): +44 (0)344 892 0111 Ireland NPIC: +353 (0)1 809 2566
For members of Public; NHS 111 in England: 111, NHS 24 in Scotland: 111, NHS Direct in Wales: 111 or 0845 4647, Ireland NPIC: +353 (0)1 809 2166(8 am to 10 pm)
3E Company; (UK) 0 800 680 0425 (GB) +44 20 35147487 (AU) +61 2 80363166 *Kuraray Access Code: 334674

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Additional information**
Medical devices as defined in Regulation (EU) 2017/745 and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (GB CLP/ GHS) usually if they are in the finished state and intended for the final user.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**

GHS07
- **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.
P264 Wash thoroughly after handling.

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- 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.
P362+P364 Take off contaminated clothing and wash it before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
P337+P313 If eye irritation persists: Get medical advice/attention.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 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 | ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | |

Other ingredients:

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

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **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:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

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- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** See Section 8.
- **6.2 Environmental precautions:**
 - Dilute with plenty of water.
 - Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
 - Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
 - Dispose contaminated material as waste according to section 13.
 - Ensure adequate ventilation.
 - Contain spill, then place in a suitable container. Minimize dust generation. Do not flush to sewer or allow to enter waterways.
 - Vacuum or sweep material and place in a disposal container. Provide ventilation.
 - Use appropriate Personal Protective Equipment (PPE).
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
 - Ensure good ventilation/exhaustion at the workplace.
 - Prevent formation of aerosols.
 - Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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.
 - Protect from heat and direct sunlight.
 - Store in cool, dry conditions in well sealed receptacles.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 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.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **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.

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Avoid contact with the eyes and skin.

· **Respiratory protection:** Suitable respiratory protective device recommended.

· **Hand protection**



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/face protection**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Physical state**

Liquid

· **Colour:**

Yellow

· **Odour:**

Odourless

· **Melting point/freezing point:**

Not determined.

· **Boiling point or initial boiling point and boiling range**

100 °C (7732-18-5 water, distilled, conductivity or of similar purity)

Not determined.

· **Flammability**

· **Lower and upper explosion limit**

Not determined.

· **Lower:**

Not determined.

· **Upper:**

· **Flash point:**

106 °C (868-77-9 2-hydroxyethyl methacrylate)

· **Auto-ignition temperature:**

375 °C (868-77-9 2-hydroxyethyl methacrylate)

· **Decomposition temperature:**

Not applicable.

· **pH at 20 °C**

≤2.5

· **Kinematic viscosity**

Not determined.

· **Solubility**

· **water:**

Fully miscible.

· **Partition coefficient n-octanol/water (log value)**

Not applicable.

· **Vapour pressure at 20 °C:**

23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)

· **Density at 20 °C:**

1 g/cm³

· **Relative vapour density**

Not determined.

· **Particle characteristics**

Not applicable.

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· 9.2 Other information

· Information with regard to physical hazard classes

| | |
|---|---|
| · Explosives | Product does not present an explosion hazard. |
| · Flammable gases | Void |
| · Aerosols | Void |
| · Oxidising gases | Void |
| · Gases under pressure | Void |
| · Flammable liquids | Void |
| · Flammable solids | Void |
| · Self-reactive substances and mixtures | Void |
| · Pyrophoric liquids | Void |
| · Pyrophoric solids | Void |
| · Self-heating substances and mixtures | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids | Void |
| · Oxidising solids | Void |
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

868-77-9 2-hydroxyethyl methacrylate

| | | |
|--------|------|--------------------------|
| Oral | LD50 | 4,680 mg/kg (guinea pig) |
| | | 3,275 mg/kg (mouse) |
| | | 5,050 mg/kg (rat) |
| | | |
| Dermal | LD50 | 5,000 mg/kg (rabbit) |

- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.

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- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**

· Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **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.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:**
Dispose of packaging according to regulations on the disposal of packagings.
Waste Framework Directive (Directive 2008/98/EC on waste)
[No. 064-B, 064-P] Packing inside the cap of the bottle case contains 0.1% or more each of SVHC.
1. Octamethylcyclotetrasiloxane (D4) (CAS 556-67-2)
2. Decamethylcyclopentasiloxane (D5) (CAS 541-02-6)
3. Dodecamethylcyclohexasiloxane (D6) (CAS 540-97-6)
SCIP number: 7fe833ae-2c52-4800-b781-d4da494eb60a
The SCIP number shall be communicated down to waste operators of the product.
For more information about the directive, visit ECHA website: <https://echa.europa.eu/understanding-wfd>
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- | | |
|--|------|
| · 14.1 UN number or ID number | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · ADR, IMDG, IATA | |
| · Class | Void |

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| | |
|--|-----------------|
| · 14.4 Packing group | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

· Regulated explosives precursors

None of the ingredients is listed.

· Regulated poisons

None of the ingredients is listed.

· Reportable explosives precursors

None of the ingredients is listed.

· Reportable poisons

None of the ingredients is listed.

· **Directive 94/33/EC:** Care should be taken when people under 18 handle this product.

· **Directive 94/85/EEC:** No further relevant information available.

· **Named dangerous substances - ANNEX I** None of the ingredient is listed.

· Regulation (EU) No 649/2012

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

· Regulation (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone-depleting potential)

None of the ingredients is listed.

· Waste Framework Directive (Directive 2008/98/EC on waste)

[No. 064-B, 064-P] Packing inside the cap of the bottle case contains 0.1% or more each of SVHC.

1. Octamethylcyclotetrasiloxane (D4) (CAS 556-67-2)

2. Decamethylcyclopentasiloxane (D5) (CAS 541-02-6)

3. Dodecamethylcyclohexasiloxane (D6) (CAS 540-97-6)

SCIP number: 7fe833ae-2c52-4800-b781-d4da494eb60a

The SCIP number shall be communicated down to waste operators of the product.

For more information about the directive, visit ECHA website: <https://echa.europa.eu/understanding-wfd>

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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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This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

· Relevant phrases

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

· Classification according to Regulation (EC) No 1272/2008

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

· Abbreviations and acronyms:

ELINCS: European List of Notified Chemical Substances

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

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

Skin Sens. 1: Skin sensitisation – Category 1

· * Data compared to the previous version altered.

GB