

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 trough 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:

Not determined.

· 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

Fully miscible.

· water:

Not applicable.

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

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

· Vapour pressure at 20 °C:

1 g/cm³

· Density at 20 °C:

Not determined.

· Relative vapour density

Not applicable.

· Particle characteristics

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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.

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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	Void
· ADR, ADN, IMDG, IATA	
· 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 Sheets 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.

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