

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

- **1.1 Product identifier**
- **Trade name:** CLEARFIL SE BOND ; BOND
- **Article number:** 064-B
- **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.
Repr. 1B H360 May damage fertility or the unborn child.
- **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 GHS08
- **Signal word** Danger
- **Hazard-determining components of labelling:**
2-hydroxyethyl methacrylate
diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

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H360 May damage fertility or the unborn child.

Precautionary statements

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing 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.
 P308+P313 IF exposed or concerned: Get medical advice/attention.
 P321 Specific treatment (see on this label).
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P405 Store locked up.
 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	20 - 40%
EINECS: 212-782-2	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide	< 3%
EINECS: 278-355-8	⚠ Repr. 1B, H360	

Other ingredients:

Bisphenol A diglycidylmethacrylate
 Hydrophobic aliphatic dimethacrylate
 Amorphous silica
 10-Methacryloyloxydecyl dihydrogen phosphate
 Accelerator
 dl-Camphorquinone

SVHC

75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide
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- **Additional information:** Silicon oxide; Nanoform, Amorphous silica, particle size 1 - 100 nm

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.

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- **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.
- **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.
Open and handle receptacle with care.
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:** Keep respiratory protective device available.
- **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.

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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.
 Store protective clothing separately.
 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** 213 °C (868-77-9 2-hydroxyethyl methacrylate)
- **Flammability** Not determined.

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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 08.07.2024

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· Lower and upper explosion limit	
· 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	Not determined.
· Kinematic viscosity	Not determined.
· Solubility	
· water:	Not miscible or difficult to mix.
· Partition coefficient n-octanol/water (log value)	Not applicable.
· Vapour pressure at 68 °C:	1.3 hPa (868-77-9 2-hydroxyethyl methacrylate)
· Density at 20 °C:	1.1 g/cm ³
· Relative vapour density	Not determined.
· Particle characteristics	Not applicable.

· 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.

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· **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)

75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

Oral	LD50	2,000 mg/kg (rat)
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· **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**

May damage fertility or the unborn child.

· **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.

· **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] Packing inside the bottle cap contains 0.1% or more each of SVHC.

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

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2. Decamethylcyclopentasiloxane (D5) (CAS 541-02-6)
 SCIP number: 1325379d-44c7-4d00-8a24-b48295dc74c7
 [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: 7fe833ac-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
· 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.

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· **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.

· **Additional classification according to Decree on Hazardous Materials, Annex II:**

· **Substances of very high concern (SVHC) according to REACH, Article 57**

75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

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

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

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

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

SCIP number: 1325379d-44c7-4d00-8a24-b48295dc74c7

[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.

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.

H360 May damage fertility or the unborn child.

· **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

SVHC: Substances of Very High Concern

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

Repr. 1B: Reproductive toxicity – Category 1B

· *** Data compared to the previous version altered.**