

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:

[Malta] National poisons helpline; 1774 to the public from Monday to Sunday between 8:00 and 20:00

3E Company; (Great Britain)+44 20 35147487 (United Kingdom)800 680 0425 (UK English)+44 8 08 189

0979 (Europe Non-Specific)+1 760 476 3962 *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 (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 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.

H360 May damage fertility or the unborn child.

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· **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 EINECS: 212-782-2	2-hydroxyethyl methacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	20 - 40%
CAS: 75980-60-8 EINECS: 278-355-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide ⚠ Repr. 1B, H360; ⚠ Skin Sens. 1B, H317	< 3%

· **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.

· **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.

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- 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:** No special measures required.
- **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.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **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

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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 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**

213 °C (868-77-9 2-hydroxyethyl methacrylate)

· **Flammability**

Not determined.

· **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/cm³

· **Relative vapour density**

Not determined.

· **Particle characteristics**

See Section 3.

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Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 25.12.2024

Version number 1

Revision date: 25.12.2024

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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** No hazardous reaction when handled and stored according to provisions.
- **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** Void

· 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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- **Primary irritant effect:**
- **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.

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- **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)
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>

SECTION 14: Transport information

- **14.1 UN number or ID number**
- **ADR, ADN, IMDG, IATA** Void

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|---|-----------------|
| · 14.2 UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· ADR, ADN, 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**
- **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.

· **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.

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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

Skin Sens. 1B: Skin sensitisation – Category 1B

Repr. 1B: Reproductive toxicity – Category 1B

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