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

Printing date 03.02.2025 Version number 2 (replaces version 1) Revision date: 03.02.2025

SECTION 1: Auðkenning efnisins eða blöndunnar og félagsins eða fyrirtækisins

· **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:**
[Iceland] Poison Center; (+354) 543 2222, (+354) 543 1000
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

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SECTION 2: Hættugreining

· **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 (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

· **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.
P280	Wear protective gloves / eye protection / face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.

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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.

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SECTION 3: Samsetning innihaldsefna/upplýsingar um innihaldsefni

· **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	15 - 40%

· **Additional information:** Silicon oxide; Nanoform, Amorphous silica, particle size 1 - 100 nm

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SECTION 4: Ráðstafanir í skyndihjálp

· **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: Ráðstafanir vegna slökkviaðgerða

· **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.

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SECTION 6: Ráðstafanir ef efni fer óvart til spillis eða er losað fyrir slysni

· **6.1 Personal precautions, protective equipment and emergency procedures** See Section 8.
· **6.2 Environmental precautions:** No special measures required.

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· **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.

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SECTION 7: Meðhöndlun og geymsla

· **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.
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: Váhrifavarnir/persónuhlífar

· **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.
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.

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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

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SECTION 9: Eðlis- og efnafræðilegir eiginleikar

· **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:**	Miscible.
· **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.
· **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

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· **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

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SECTION 10: Stöðugleiki og hvarfgirni

· **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

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SECTION 11: Eiturefnafræðilegar upplýsingar

· **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)

· **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.
· **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.
· **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: Vistfræðilegar upplýsingar

· **12.1 Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **12.2 Persistence and degradability** No further relevant information available.

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· **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: Förgun

· **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: Upplýsingar um flutninga

· **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, 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.

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· **UN "Model Regulation":** Void

SECTION 15: Upplýsingar varðandi regluverk

· **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.

· **Waste Framework Directive (Divective 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: Aðrar upplýsingar

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 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.**