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

Printing date 06.01.2026 Version number 2 (replaces version 1) Revision date: 06.01.2026

*
SECTION 1: Auðkenning efnisins eða blöndunnar og félagsins eða fyrirtækisins

· **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:**
[Iceland] Poison Center; (+354) 543 2222, (+354) 543 1000
[3E Company] (Great Britain (London))+44 20 351 47487, (United Kingdom - Domestic)+44 800 680 0425, (United Kingdom - International)+44 808 189 0979 (Europe Non-Specific)+1 760 476 3962 *Kuraray Access Code: 334674

*
SECTION 2: Hættugreining

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
Skin Corr. 1 H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.
Skin Sens. 1 H317 May cause an allergic skin reaction.

· **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**

GHS05 GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**
2-hydroxyethyl methacrylate
· **Hazard statements**
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
· **Precautionary statements**

P260	Do not breathe dusts or mists.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.

(Contd. on page 2)

Trade name: CLEARFIL SE BOND ; PRIMER

(Contd. of page 1)

P321	Specific treatment (see on this label).
P362+P364	Take off contaminated clothing and wash it before reuse.
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: 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	10-30%

*
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. Then consult a doctor.
· **After swallowing:** Drink plenty of water and provide fresh air. Call for a doctor immediately.
· **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**
During heating or in case of fire poisonous gases are produced.
· **5.3 Advice for firefighters**
· **Protective equipment:** Mouth respiratory protective device.

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

· **6.1 Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
Wear protective equipment. Keep unprotected persons away.
See Section 8.
· **6.2 Environmental precautions:**
Before cleaning, pre-clean the equipment under running water with a damp cloth.
Avoid disposing of uncured product residues into the sewage system.

(Contd. on page 3)

Trade name: CLEARFIL SE BOND ; PRIMER

(Contd. of page 2)

· **6.3 Methods and material for containment and cleaning up:**
Use neutralising agent.
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
Absorb liquid components with liquid-binding material.
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: 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:** 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: 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:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
Suitable respiratory protective device recommended.
· **Hand protection**

Protective gloves

(Contd. on page 4)

Trade name: CLEARFIL SE BOND ; PRIMER

(Contd. of page 3)

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: Eðlis- og efnafræðilegir eiginleikar

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	Liquid
· **Colour:**	Orange
· **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)
· **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 at 20 °C**	2
· **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.
· **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

(Contd. on page 5)

Trade name: CLEARFIL SE BOND ; PRIMER

(Contd. of page 4)

· **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: 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

*
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)

· **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
· **Serious eye damage/irritation** Causes serious eye damage.
· **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.

(Contd. on page 6)

Trade name: CLEARFIL SE BOND ; PRIMER

(Contd. of page 5)

· **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.
Must not reach sewage water or drainage ditch undiluted or unneutralised.

*
SECTION 13: Förgun

· **13.1 Waste treatment methods**
· **Recommendation**
Dispose of this product as medical waste.
Mix residues on disposable materials (e.g. paper, tray) and dispose of them as solid waste.
Uncured product residues should be cured before disposal if possible.

· **Uncleaned packaging:**
· **Recommendation:**
Dispose of packaging according to regulations on the disposal of packagings.
Non contaminated packagings may be recycled.
Do not rinse product containers before disposal.
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

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

(Contd. on page 7)

Trade name: CLEARFIL SE BOND ; PRIMER

(Contd. of page 6)

· **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) 2019/1021 on persistent organic pollutants (POP)**
None of the ingredients is listed.

· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **Regulation (EU) No 649/2012**
None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**
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 (EU) 2024/590 on substances that deplete the ozone layer**
None of the ingredients is listed.

· **Waste Framework Directive (Divective 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: 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.
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.
This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

· **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 Corr. 1: Skin corrosion/irritation – Category 1
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

(Contd. on page 8)

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

Printing date 06.01.2026 Version number 2 (replaces version 1) Revision date: 06.01.2026

Trade name: CLEARFIL SE BOND ; PRIMER

(Contd. of page 7)

Skin Sens. 1: Skin sensitisation – Category 1

· **Relevant phrases**
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

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