

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

- Trade name: CLEARFIL SE BOND 2 ; PRIMER
- Article number: 195-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] (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: Hazards identification**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 GB 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].

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- 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.
 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: 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	15-40%
EINECS: 212-782-2	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	

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. 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: 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**
During heating or in case of fire poisonous gases are produced.
- **5.3 Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
Wear protective equipment. Keep unprotected persons away.

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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.

· 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: 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: 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

Wash hands before breaks and at the end of work.

Avoid contact with the eyes.

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.

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· 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:	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/cm ³
· Relative vapour density	Not determined
· Particle characteristics	Not applicable.

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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** 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.

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· 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.

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

SECTION 13: Disposal considerations
· 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.

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

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|--|----------------|
| · 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) 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.

· 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.

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.

This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

The concentration ranges for dangerous components in Section 3.2 are based on UK REACH Annex II 3.2 and adopt the ranges from the Canada HPR (Hazardous Products Regulations) Section 4.4.1(3) and the US HCS (Hazard Communication Standard) §1910.1200(i)(1)(iv). The concentration ranges listed in this SDS may differ from those provided in the European IFU (Instructions for Use).

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· 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
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.

GB