

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

- **1.1 Product identifier**
- **Trade name:** CLEARFIL SE Protect ; PRIMER
- **Article number:** 092-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
2-dimethylaminoethyl 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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Trade name: CLEARFIL SE Protect ; PRIMER

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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	
CAS: 2867-47-2	2-dimethylaminoethyl methacrylate	1-7%
EINECS: 220-688-8	⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; 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.

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Trade name: CLEARFIL SE Protect ; PRIMER

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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.

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 and skin.

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Trade name: CLEARFIL SE Protect ; PRIMER

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· 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

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:

Light blue

· 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)

Not determined

· Flammability
· 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:

Partly 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:
1.1 g/cm³

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Trade name: CLEARFIL SE Protect ; PRIMER

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· 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** 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, carbon dioxide and nitrogen oxides
Phosphorus oxides (e.g. P₂O₅)

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)

2867-47-2 2-dimethylaminoethyl methacrylate

Oral	LD50	1,751 mg/kg (rat)
Inhalative	LC50/4 h	0.62 mg/l (rat)
	LD50	25 mg/kg (mouse - intraperitoneal)

- **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.

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Trade name: CLEARFIL SE Protect ; PRIMER

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- **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
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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.
 Waste Framework Directive (Directive 2008/98/EC on waste)
 [No. 092-B, 092-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: bba7f05a-95bf-4e4b-8008-11f8e8b23f47
 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>

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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) 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.

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· **REGULATION (EU) 2024/590 on substances that deplete the ozone layer**

None of the ingredients is listed.

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

[No. 092-B, 092-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: bba7f05a-95bf-4e4b-8008-11f8e8b23f47

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.

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 Sheet 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).

· **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

Acute Tox. 4: Acute toxicity – Category 4

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**

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

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

**Safety data sheet
according to UK REACH**

Printing date 03.10.2024

Version number 11 (replaces version 10)

Revision date: 03.10.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** CLEARFIL SE Protect ; BOND**Article number:** 092-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; (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.

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

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.

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Trade name: CLEARFIL SE Protect ; BOND

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

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: 7681-49-4	sodium fluoride	< 1%
EINECS: 231-667-8	⚠ Acute Tox. 3, H301; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319, EUH032	

- **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.
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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Safety data sheet according to UK REACH

Printing date 03.10.2024

Version number 11 (replaces version 10)

Revision date: 03.10.2024

Trade name: CLEARFIL SE Protect ; BOND

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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.
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.
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.

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 and skin.
- **Respiratory protection:** Suitable respiratory protective device recommended.

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Safety data sheet according to UK REACH

Printing date 03.10.2024

Version number 11 (replaces version 10)

Revision date: 03.10.2024

Trade name: CLEARFIL SE Protect ; BOND

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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:	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/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.

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· 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 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.

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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.

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. 092-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: 289a160f-a790-4c43-ab94-4b77b8508ce7

[No. 092-B, 092-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: bba7f05a-95bf-4e4b-8008-11f8e8b23f47

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

· 14.2 UN proper shipping name**· ADR, ADN, IMDG, IATA**

Void

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- | | |
|---|-----------------|
| · 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**

7681-49-4 sodium fluoride

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.

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

[No. 092-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: 289a160f-a790-4c43-ab94-4b77b8508ce7

[No. 092-B, 092-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: bba7f05a-95bf-4e4b-8008-11f8e8b23f47

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· **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**

H301 Toxic if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

EUH032 Contact with acids liberates very toxic gas.

· **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

Acute Tox. 3: Acute toxicity – Category 3

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.**

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