

Safety Data Sheet
according to HPR, Schedule 1

Printing date 09/25/2023

Version 4

Reviewed on 09/25/2023

1 Identification

- **Product identifier**
- **Trade name:** CLEARFIL SE PROTECT ; PRIMER
- **Article number:** CA092-P
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Dental bonding material
- **Details of the supplier of the safety data sheet**
- **Supplier**
Kuraray America, Inc.
32 Old Slip, 7th Floor, New York,
NY 10005 U.S.A.
Tel: 800-879-1676
Website: www.kuraraydental.com
- **Further information obtainable from:** Supplier
- **Emergency telephone number:**
CHEMTREC; day and night, within USA and Canada
1-800-424-9300 CCN706984 or +1 703-527-3887 (collect calls accepted)

2 Hazard identification

- **Classification of the substance or mixture**
Skin Irritation - Category 2 H315 Causes skin irritation.
Eye Irritation - Category 2A H319 Causes serious eye irritation.
Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.
Reproductive Toxicity - Category 2 H361 Suspected of damaging fertility or the unborn child.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07 GHS08

- **Signal word** Warning
- **Hazard-determining components of labeling:**
2-hydroxyethyl methacrylate
2-dimethylaminoethyl methacrylate
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H361 Suspected of damaging fertility or the unborn child.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face 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.

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P405	Store locked up.	(Contd. of page 1)
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.	

3 Composition/Information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

868-77-9	2-hydroxyethyl methacrylate ⚠ Skin Irritation - Category 2, H315; Eye Irritation - Category 2A, H319; Skin Sensitizer - Category 1, H317	25-45% *
2867-47-2	2-dimethylaminoethyl methacrylate ⚠ Acute Toxicity (Oral) - Category 4, H302; Acute Toxicity (Dermal) - Category 4, H312; Skin Irritation - Category 2, H315; Eye Irritation - Category 2A, H319; Skin Sensitizer - Category 1, H317	1-5% *
75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide ⚠ Reproductive Toxicity - Category 2, H361	<1%

* Actual concentration ranges are withheld as a trade secret.

- **Other ingredients:**

Water
10-Methacryloyloxydecyl dihydrogen phosphate
Hydrophilic aliphatic dimethacrylate
12-Methacryloyloxydodecylpyridinium bromide
Dye

4 First-aid measures

- **Description of first aid measures**
- **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:**
Do not induce vomiting; immediately call for medical help.
If symptoms persist consult doctor.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:**
Wear self-contained respiratory protective device.

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Wear fully protective suit.

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** See Section 8.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.

7 Handling and storage

- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** No special measures required.
- **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 receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/ Personal protection

- **Control parameters**
- **Components 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 that were valid during the creation were used as basis.
- **Exposure controls**
- **Additional information about design of technical systems:** No further data; see section 7.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Breathing equipment:** Not required.
- **Protection of hands:**



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.

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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 protection:**



Tightly sealed goggles

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· Physical state	Liquid
· Color:	Blue
· Odor:	Odorless
· Melting point/Melting range:	-12 °C (2-hydroxyethyl methacrylate)
· Boiling point/Boiling range:	205°C(2-hydroxyethyl methacrylate)
· Flammability (solid, gaseous):	Not determined.
· Explosion limits:	
· Lower:	Not determined
· Upper:	Not determined
· Flash point:	97 °C (2-hydroxyethyl methacrylate)
· Auto ignition temperature:	Not determined
· Decomposition temperature:	Not determined
· pH-value:	≤2.5
· Viscosity:	Not determined
· Kinematic viscosity	Not determined.
· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix.
· Partition coefficient (n-octanol/water):	Not determined
· Vapor pressure:	Not determined
· Density:	1.1 g/cm ³
· Relative density	Not determined
· Relative vapor density	Not determined

· **Other information**

· **Important information on protection of health and environment, and on safety.**

· **Danger of explosion:** Product does not present an explosion hazard.

10 Stability and reactivity

· **Reactivity** No further relevant information available.

· **Chemical stability**

· **Thermal decomposition / conditions to be avoided:**

No decomposition if used and stored according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known.

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- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:** Based on available data, the classification criteria are not met.

LD/LC50 values that are relevant for classification:

868-77-9 2-hydroxyethyl methacrylate

Oral	LD50	4680 mg/kg (guinea pig)
		3275 mg/kg (mouse)
		5050 mg/kg (rat)

- **on the skin:** Causes skin irritation.
- **on the eye:**
Causes serious eye irritation.
- **Sensitization:**
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**
Suspected of damaging fertility or the unborn child.
- **Specific target organ toxicity - single exposure**
Based on available data, the classification criteria are not met.
- **Specific target organ toxicity - repeated exposure**
Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Subacute to chronic toxicity:**

Carcinogenic categories

IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

NTP (National Toxicology Program)

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (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.

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13 Disposal considerations

- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	
· DOT/TDG, IMDG, IATA	Void
· UN proper shipping name	
· DOT/TDG, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, IMDG, IATA	
· Class	Void
· Packing group	
· DOT/TDG, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.

· **Canadian substance listings:**

· Canadian Domestic Substances List (DSL)	
868-77-9	2-hydroxyethyl methacrylate
7732-18-5	water, distilled, conductivity or of similar purity
· Canadian Non-Domestic Substances List (NDSL)	
None of the ingredients is listed.	
· Canadian Ingredient Disclosure list (limit 0.1%)	
None of the ingredients is listed.	
· Canadian Ingredient Disclosure list (limit 1%)	
868-77-9	2-hydroxyethyl methacrylate

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.

- **Relevant phrases**
H302 Harmful if swallowed.

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H312 Harmful in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H361 Suspected of damaging fertility or the unborn child.

· **Abbreviations and acronyms:**

DOT: US Department of Transportation

ELINCS: European List of Notified Chemical Substances

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

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