

1 Identification

- **Product identifier**
- **Trade name:** CLEARFIL SE Protect ; PRIMER
- **Article number:** US092-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 materials
- **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
- **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(s) identification

- **Classification of the substance or mixture**
Skin Irritation 2 H315 Causes skin irritation.
Eye Irritation 2A H319 Causes serious eye irritation.
Sensitization - Skin 1 H317 May cause an allergic skin reaction.
Toxic to Reproduction 1B H360 May damage 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** Danger
- **Hazard-determining components of labeling:**
2-hydroxyethyl methacrylate
diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide
2-dimethylaminoethyl methacrylate
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H360 May damage fertility or the unborn child.

· **Precautionary statements**

- P261 Avoid breathing dust/fume/gas/mist/vapors/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).
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P363 Wash contaminated clothing before reuse.

(Contd. on page 2)

Trade name: CLEARFIL SE Protect ; PRIMER

(Contd. of page 1)

P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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 2, H315; Eye Irritation 2A, H319; Sensitization - Skin 1, H317	25 - 45%
2867-47-2	2-dimethylaminoethyl methacrylate ⚠ Acute Toxicity - Oral 4, H302; Acute Toxicity - Dermal 4, H312; Skin Irritation 2, H315; Eye Irritation 2A, H319; Sensitization - Skin 1, H317	< 5%
75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide ⚠ Toxic to Reproduction 1B, H360; ⚠ Sensitization - Skin 1B, H317	< 1%

4 First-aid measures

- **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.
- **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.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** See Section 8.
- **Environmental precautions:** Dilute with plenty of water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

(Contd. on page 3)

Trade name: CLEARFIL SE Protect ; PRIMER

(Contd. of page 2)

- 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).
- **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.
- Open and handle receptacle with care.
- 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 protection against explosions and fires:** Keep respiratory protective device available.
- **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.
- Protect from heat and direct sunlight.
- Store in cool, dry conditions in well sealed receptacles.
- **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:**
- Keep away from foodstuffs, beverages and feed.
- Immediately remove all soiled and contaminated clothing.
- Wash hands before breaks and at the end of work.
- Store protective clothing separately.
- Avoid contact with the eyes and skin.
- **Breathing equipment:** Suitable respiratory protective device recommended.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

(Contd. on page 4)

Trade name: CLEARFIL SE Protect ; PRIMER

(Contd. of page 3)

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 protection:**



Tightly sealed goggles

9 Physical and chemical properties

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

· **General Information**

· **Physical state**

Liquid

· **Color:**

Light blue

· **Odor:**

Odorless

· **Odor threshold:**

Not determined.

· **Melting point/Melting range:**

Not determined.

· **Boiling point/Boiling range:**

100 °C (7732-18-5 water, distilled, conductivity or of similar purity)

· **Flammability:**

Not determined.

· **Explosion limits:**

· **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-value at 20 °C:**

≤2.5

· **Viscosity:**

· **Kinematic viscosity**

Not determined.

· **Dynamic:**

Not determined.

· **Solubility in / Miscibility with**

· **Water:**

Partly miscible.

· **Partition coefficient (n-octanol/water):**

Not applicable.

· **Vapor pressure at 20 °C:**

23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)

· **Density at 20 °C:**

1.1 g/cm³

· **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.

(Contd. on page 5)

Trade name: CLEARFIL SE Protect ; PRIMER

(Contd. of page 4)

· **Evaporation rate** Not determined.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** No hazardous reaction when handled and stored according to provisions.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **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	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)

- **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**
May damage 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.

Trade name: CLEARFIL SE Protect ; PRIMER

(Contd. of page 5)

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.

13 Disposal considerations

- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Dispose of packaging according to regulations on the disposal of packagings.

14 Transport information

· UN-Number	
· DOT, IMDG, IATA	Void
· UN proper shipping name	
· DOT, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, IMDG, IATA	Void
· Environmental hazards:	Not applicable.
· 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**
- **Sara**

· **Section 355 (extremely hazardous substances):**
None of the ingredient is listed.

(Contd. on page 7)

Trade name: CLEARFIL SE Protect ; PRIMER

(Contd. of page 6)

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· SARA 311/312: See Section 2 for the information on physical and health hazards.

· TSCA (Toxic Substances Control Act):

868-77-9	2-hydroxyethyl methacrylate	ACTIVE
2867-47-2	2-dimethylaminoethyl methacrylate	ACTIVE
75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide	ACTIVE

· Hazardous Air Pollutants

None of the ingredients is listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Cancerogenity categories :

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value)

None of the ingredients is listed.

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.
- H312 Harmful in contact with skin.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H360 May damage fertility or the unborn child.

· NFPA ratings (scale 0 - 4)

Health = 2
Fire = 1
Reactivity = 0

· HMIS-ratings (scale 0 - 4)

HEALTH	2	Health = 2
FIRE	1	Fire = 1
REACTIVITY	0	Reactivity = 0

· Abbreviations and acronyms:

- DOT: US Department of Transportation
- ELINCS: European List of Notified Chemical Substances
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit

(Contd. on page 8)

Safety Data Sheet
acc. to OSHA HCS

Printing date 10/02/2024

Version 5

Reviewed on 10/02/2024

Trade name: CLEARFIL SE Protect ; PRIMER

Acute Toxicity - Oral 4: Acute toxicity – Category 4
Skin Irritation 2: Skin corrosion/irritation – Category 2
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
Sensitization - Skin 1: Skin sensitisation – Category 1
Sensitization - Skin 1B: Skin sensitisation – Category 1B
Toxic to Reproduction 1B: Reproductive toxicity – Category 1B

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

(Contd. of page 7)

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