

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

- **Product identifier**
- **Trade name:** CLEARFIL SE Protect ; PRIMER
- **Article number:** US092-P
- **Application of the substance / the preparation** Dental bonding material
- **Details of the supplier of the safety data sheet**
- **Manufacturer:**
Kuraray Noritake Dental Inc.
1621 Sakazu, Kurashiki, Okayama 710-0801,
Japan
- **Contact information:**
Kuraray America, Inc.
33 Maiden Lane, 6th Floor, New York,
NY 10038 U.S.A.
Tel: 800-879-1676
Fax: 888-700-5200
Website: www.kuraraydental.com

2 Composition/information on ingredients

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

· **Dangerous components:**

868-77-9	2-hydroxyethyl methacrylate	25-45%
	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	

- **Other ingredients:**
10-Methacryloyloxydecyl dihydrogen phosphate
12-Methacryloyloxydodecylpyridinium bromide
Hydrophilic aliphatic dimethacrylate
Water
Initiators
Accelerators
Dyes

3 Hazards identification

- **Classification of the substance or mixture**



- Skin Irrit. 2 H315 Causes skin irritation.
- Eye Irrit. 2A H319 Causes serious eye irritation.
- Skin Sens. 1 H317 May cause an allergic skin reaction.

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

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H317 May cause an allergic skin reaction.

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.
- P321 Specific treatment (see on this label).
- P362 Take off contaminated clothing and wash before reuse.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Classification system:

NFPA ratings (scale 0 - 4)



Health = 1
Fire = 1
Reactivity = 0

HMIS-ratings (scale 0 - 4)



Health = 1
Fire = 1
Reactivity = 0

4 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.

5 Firefighting measures

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.

Protective equipment:

Wear self-contained respiratory protective device.
Wear fully protective suit.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures Not required.

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.

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See Section 13 for disposal information.

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7 Handling and storage

- **Handling:**
- **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.
- **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.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **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.
- **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. 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 protection:**



Tightly sealed goggles

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9 Physical and chemical properties

· General Information	
· Appearance:	
Form:	Liquid
Color:	Blue
· Odor:	Odorless
· pH-value:	<2.5
· Change in condition	
Melting point/Melting range:	-12 °C (2-hydroxyethyl methacrylate)
Boiling point/Boiling range:	205 °C (2-hydroxyethyl methacrylate)
· Flash point:	97 °C (2-hydroxyethyl methacrylate)
· Ignition temperature:	Not applicable
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not applicable
Upper:	Not applicable
· Vapor pressure:	Not applicable
· Density:	1.1 g/cm ³
· Vapour density	Not applicable
· Solubility in / Miscibility with	
Water:	Not miscible or difficult to mix.
· Partition coefficient (n-octanol/water):	Not applicable
· Other information	No further relevant information available.

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

11 Toxicological information

- **Acute toxicity:**

- **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)

- **Primary irritant effect:**
- **on the skin:** Irritating effect
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

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· **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

- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **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

- **Waste treatment methods**
- **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, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, 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": | - |

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15 Regulatory information

· **Sara**

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

· Section 313 (Specific toxic chemical listings):
None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):
All ingredients are 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.

· **Carcinogeny categories**

· EPA (Environmental Protection Agency)
None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)
None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)
None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)
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.

· **Version: 2**

· **Relevant phrases**

- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.