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Reviewed on 04/01/2012

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:** Single Component
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

868-77-9	2-hydroxyethyl methacrylate	 H315; H319; H317	25-45%
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· **Other ingredients:**

10-Methacryloyloxydecyl dihydrogen phosphate
 12-Methacryloyloxydodecylpyridinium bromide
 Hydrophilic aliphatic dimethacrylate
 Water
 Initiators
 Accelerators
 Dyes
 Others

3 Hazards identification

- **Classification of the substance or mixture**



GHS05 Corrosion

H314 Causes severe skin burns and eye damage.



GHS07

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Irritant

Irritating to eyes and skin. May cause sensitisation by skin contact.

- **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of international guidelines.

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· **Classification system:**

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· **Label elements**· **GHS label elements**

The product is classified and labelled according to the Globally Harmonized System (GHS).

· **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 dust/fume/gas/mist/vapours/spray.

P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

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 or doctor/physician.

P405 Store locked up.

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.

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- **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.
See Section 13 for disposal information.

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

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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· **General Information**· **Appearance:**

Form:	Liquid
Color:	Transparent Blue

· **Odor:** Odorless· **pH-value:** 2.0· **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/cm³ (9.18 lbs/gal)· **Vapour density:** Not applicable· **Solubility in / Miscibility with**

Water: Not miscible or difficult to mix.

· **Segregation 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

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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:** Irritant to skin and mucous membranes.· **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

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

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- | | |
|---|-----------------|
| · 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": | - |

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.

· Cancerogenity categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· IARC (International Agency for Research on Cancer)

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.

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