

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

074576963

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

074576930 074576948 075217724

## 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.

(Contd. on page 2)

—USA

**Trade name: CLEARFIL SE Protect ; PRIMER**

(Contd. of page 1)

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

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- **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.

(Contd. on page 3)

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**Trade name: CLEARFIL SE Protect ; PRIMER**

(Contd. of page 2)

- **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

(Contd. on page 4)

USA

**Trade name: CLEARFIL SE Protect ; PRIMER**

(Contd. of page 3)

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/cm<sup>3</sup> (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

USA

(Contd. on page 5)

**Trade name: CLEARFIL SE Protect ; PRIMER**

(Contd. of page 4)

**11 Toxicological information**

· **Acute toxicity:**

· <b>LD/LC50 values that are relevant for classification:</b>		
<b>868-77-9 2-hydroxyethyl methacrylate</b>		
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**

· <b>UN-Number</b>	
· <b>DOT, ADR, ADN, IMDG, IATA</b>	Void
· <b>UN proper shipping name</b>	
· <b>DOT, ADR, ADN, IMDG, IATA</b>	Void
· <b>Transport hazard class(es)</b>	
· <b>DOT, ADR, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>Packing group</b>	
· <b>DOT, ADR, IMDG, IATA</b>	Void

(Contd. on page 6)

USA

**Trade name: CLEARFIL SE Protect ; PRIMER**

(Contd. of page 5)

- **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.

· **Carcinogeny 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.

**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.



**Trade name: CLEARFIL SE Protect ; PRIMER**

(Contd. of page 1)

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.

(Contd. on page 3)

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**Trade name: CLEARFIL SE Protect ; PRIMER**

See Section 13 for disposal information.

(Contd. of page 2)

## 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

USA

(Contd. on page 4)

**Trade name: CLEARFIL SE Protect ; PRIMER**

(Contd. of page 3)

## 9 Physical and chemical properties

· <b>General Information</b>	
· <b>Appearance:</b>	
<b>Form:</b>	Liquid
<b>Color:</b>	Blue
· <b>Odor:</b>	Odorless
· <b>pH-value:</b>	<2.5
· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	-12 °C (2-hydroxyethyl methacrylate)
<b>Boiling point/Boiling range:</b>	205 °C (2-hydroxyethyl methacrylate)
· <b>Flash point:</b>	97 °C (2-hydroxyethyl methacrylate)
· <b>Ignition temperature:</b>	Not applicable
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not applicable
<b>Upper:</b>	Not applicable
· <b>Vapor pressure:</b>	Not applicable
· <b>Density:</b>	1.1 g/cm <sup>3</sup>
· <b>Vapour density</b>	Not applicable
· <b>Solubility in / Miscibility with</b>	
<b>Water:</b>	Not miscible or difficult to mix.
· <b>Partition coefficient (n-octanol/water):</b> Not applicable	
· <b>Other information</b> 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

(Contd. on page 5)

**Trade name: CLEARFIL SE Protect ; PRIMER**

(Contd. of page 4)

· **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**

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

Printing date 05/01/2016

Reviewed on 05/01/2016

**Trade name: CLEARFIL SE Protect ; PRIMER**

(Contd. of page 5)

**15 Regulatory information**

· **Sara**

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

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

· <b>TSCA (Toxic Substances Control Act):</b>
All ingredients are listed.

· **Proposition 65**

· <b>Chemicals known to cause cancer:</b>
None of the ingredients is listed.

· <b>Chemicals known to cause reproductive toxicity for females:</b>
None of the ingredients is listed.

· <b>Chemicals known to cause reproductive toxicity for males:</b>
None of the ingredients is listed.

· <b>Chemicals known to cause developmental toxicity:</b>
None of the ingredients is listed.

· **Carcinogenicity categories**

· <b>EPA (Environmental Protection Agency)</b>
None of the ingredients is listed.

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

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

· <b>OSHA-Ca (Occupational Safety &amp; Health Administration)</b>
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.