

Printing date 03/09/2015

Reviewed on 04/01/2015

1 Identification

- **Product identifier**
- **Trade name:** CLEARFIL SE PROTECT ; BOND
- **Article number:** CA092-B
- **Application of the substance / the mixture** 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:**

1565-94-2	bisphenol A diglycidylmethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319	25-50%
868-77-9	2-hydroxyethyl methacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	25-50%
7681-49-4	sodium fluoride ☠ Acute Tox. 3, H301; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	≤2.5%

- **Other ingredients:**
10-Methacryloyloxydecyl dihydrogen phosphate
Hydrophobic aliphatic methacrylate
Colloidal silica
dl-Camphorquinone
Initiators
Accelerators

3 Hazard(s) identification

- **Classification of the substance or mixture**



GHS07

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 labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labeling:**
2-hydroxyethyl methacrylate

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Hazard statements

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

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapors/spray
P280 Wear protective gloves.
P280 Wear 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).
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard description:**WHMIS-symbols:**

D2B - Toxic material causing other toxic effects

**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 Fire-fighting 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.

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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

- **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.
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

- **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.

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· **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
Yellow

· **Odor:** Odorless· **pH-value:** Not applicable· **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· **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

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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)

7681-49-4 sodium fluoride

Oral	LD50	44 mg/kg (mouse)
		52 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

· **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.

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

None of the ingredients is listed.

12 Ecological information· **Persistence and degradability** No further relevant information available.· **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, TDG, ADN, IMDG, IATA** Void

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· UN proper shipping name	
· DOT, TDG, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, TDG, ADN, 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":	-

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.

· 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.

· Canadian substance listings:

· Canadian Domestic Substances List (DSL)

All ingredients are listed.

· Canadian Ingredient Disclosure list (limit 0.1%)

None of the ingredients is listed.

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· Canadian Ingredient Disclosure list (limit 1%)

868-77-9	2-hydroxyethyl methacrylate
7681-49-4	sodium fluoride

16 Other information**· Version: 2****· Relevant phrases**

H301 Toxic if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

· Abbreviations and acronyms:

Acute Tox. 3: Acute toxicity, Hazard Category 3

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

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1 Identification

- **Product identifier**
- **Trade name:** CLEARFIL SE PROTECT ; PRIMER
- **Article number:** CA092-P
- **Application of the substance / the mixture** 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 Hazard(s) identification

- **Classification of the substance or mixture**



GHS07

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 labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labeling:**
2-hydroxyethyl methacrylate
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.

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Trade name: CLEARFIL SE PROTECT ; PRIMER

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H317 May cause an allergic skin reaction.

Precautionary statements

- P261 Avoid breathing dust/fume/gas/mist/vapors/spray
P280 Wear protective gloves.
P280 Wear 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).
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard description:**WHMIS-symbols:**

D2B - Toxic material causing other toxic effects

**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 Fire-fighting 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.

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Trade name: CLEARFIL SE PROTECT ; PRIMER

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- **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.
- **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

- **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.

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Trade name: CLEARFIL SE PROTECT ; PRIMER

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· Eye protection:



Tightly sealed goggles

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/cm³

· 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)

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Trade name: CLEARFIL SE PROTECT ; PRIMER

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- **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
- **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.

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

None of the ingredients is listed.

12 Ecological information

- **Persistence and degradability** No further relevant information available.
- **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, TDG, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, TDG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, TDG, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, TDG, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |

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- | | |
|--|-----------------|
| · 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.

· **Carcinogen 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.

· **Canadian substance listings:**· **Canadian Domestic Substances List (DSL)**

All ingredients are 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.

· **Version:** 2· **Relevant phrases**

H315 Causes skin irritation.

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Trade name: CLEARFIL SE PROTECT ; PRIMER

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H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Abbreviations and acronyms:

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

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