




1 Identification of substance

- **Product details**
- **Trade name:** CLEARFIL SE Protect ; BOND
- **Article number:** US092-B
- **Application of the substance / the preparation** Dental bonding material
- **Manufacturer:**
Kuraray Medical Inc.
1621 Sakazu, Kurashiki, Okayama 710-0801,
Japan
- **Supplier:**
Kuraray America, Inc.
600 Lexington Avenue, 26th Floor, New York,
NY 10022 U.S.A.
Tel: 800-879-1676
Fax: 888-700-5200
Website: www.kuraraydental.com
- **Information department:** Supplier

2 Composition/Data on components

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

- **Dangerous components:**

1565-94-2	bisphenol A diglycidylmethacrylate	Warning:  3.2/2, 3.3/2A	25-45%
868-77-9	2-hydroxyethyl methacrylate	Warning:  3.2/2, 3.3/2A, 3.4.S/1	20-40%
7681-49-4	sodium fluoride	Danger:  3.1.O/3, 3.2/2, 3.3/2A	<1%

- **Other ingredients:**

10-Methacryloyloxydecyl dihydrogen phosphate
Hydrophobic aliphatic dimethacrylate
Colloidal silica
dl-Camphorquinone
Initiators
Accelerators
Others

3 Hazards identification

- **Hazard description:**



Irritant

- **Information pertaining to particular dangers for man and environment:**

The product has to be labelled due to the calculation procedure of international guidelines.
Irritating to eyes and skin.
May cause sensitisation by skin contact.

- **Classification system:**

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

- **NFPA ratings (scale 0 - 4)**

Health = 1
Fire = 1
Reactivity = 0

(Contd. on page 2)

Trade name: CLEARFIL SE Protect ; BOND

(Contd. of page 1)

· **HMIS-ratings (scale 0 - 4)**

Health = 1
Fire = 1
Reactivity = 0

· **GHS label elements**



Warning

3.2/2 - Causes skin irritation.
3.3/2A - Causes serious eye irritation.
3.4/1 - May cause an allergic skin reaction.

· **Prevention:**

Avoid breathing dust/fume/gas/mist/vapours/spray.
Wash thoroughly after handling.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.

· **Response:**

IF ON SKIN: Wash with plenty of soap and water.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Specific treatment (see on this label).
If skin irritation occurs: Get medical advice/attention.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Take off contaminated clothing and wash before reuse.
Wash contaminated clothing before reuse.

· **Disposal:**

Dispose of contents/container in accordance with local/regional/national/international regulations.

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.

· **Protective equipment:**

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

6 Accidental release measures

· **Person-related safety precautions:** Not required.

· **Measures for environmental protection:** Do not allow to enter sewers/ surface or ground water.

(Contd. on page 3)

Printing date 09/25/2009

Reviewed on 09/25/2009

Trade name: CLEARFIL SE Protect ; BOND

(Contd. of page 2)

- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

7 Handling and storage

- **Handling:**
- **Information 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.

8 Exposure controls and 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 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

Form:	Liquid
Color:	Transparent Yellow

(Contd. on page 4)

Trade name: CLEARFIL SE Protect ; BOND

(Contd. of page 3)

Odor:	Odorless
· 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.
· pH-value:	Not applicable
· Segregation coefficient (n-octanol/water):	Not applicable

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
- **Dangerous reactions** No dangerous reactions known.
- **Dangerous products of decomposition:** 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)

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

USA

(Contd. on page 5)

Printing date 09/25/2009

Reviewed on 09/25/2009

Trade name: CLEARFIL SE Protect ; BOND

(Contd. of page 4)

12 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

- **Product:**
- **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

- **DOT regulations:**
- **Hazard class:** -
- **Land transport ADR/RID (cross-border):**
- **ADR/RID class:** -
- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -
- **UN "Model Regulation":** -

15 Regulations

- **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.

(Contd. on page 6)

Trade name: CLEARFIL SE Protect ; BOND

(Contd. of page 5)

· **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.

· **NTP (National Toxicology Program)**

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.

· **Product related hazard informations:**

The product has been classified and marked in accordance with directives on hazardous materials.

· **Hazard symbols:**



Irritant

· **Hazard-determining components of labelling:**

2-hydroxyethyl methacrylate
sodium fluoride
bisphenol A diglycidylmethacrylate

· **Risk phrases:**

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

· **Safety phrases:**

Avoid contact with skin.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
After contact with skin, wash immediately with plenty of soap and water.
Wear suitable gloves.
This material and its container must be disposed of as hazardous waste.

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: 1**

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
ACGIH: American Conference of Governmental Industrial Hygienists
NFPA: National Fire Protection Association (USA)

(Contd. on page 7)

Printing date 09/25/2009

Reviewed on 09/25/2009

Trade name: CLEARFIL SE Protect ; BOND

HMIS: Hazardous Materials Identification System (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent

(Contd. of page 6)

USA