

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

- **Product identifier**
- **Trade name:** CLEARFIL Universal Bond
- **Article number:** US194
- **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:**

1565-94-2	bisphenol A diglycidylmethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319	15-35%
868-77-9	2-hydroxyethyl methacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-35%
64-17-5	ethanol ⚠ Flam. Liq. 2, H225	<20%

- **Other ingredients:**
10-Methacryloyloxydecyl dihydrogen phosphate
Hydrophilic aliphatic dimethacrylate
Colloidal silica
dl-Camphorquinone
Silane coupling agent
Accelerators
Initiators
Water

3 Hazards identification

- **Classification of the substance or mixture**



GHS02 Flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour.



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.

(Contd. on page 2)

Printing date 10/18/2013

Reviewed on 10/18/2013

Trade name: CLEARFIL Universal Bond

(Contd. of page 1)

- **Label elements**
- **GHS label elements**
The product is classified and labelled according to the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS02, GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**
2-hydroxyethyl methacrylate
- **Hazard statements**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P241 Use explosion-proof electrical/ventilating/lighting/equipment.
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.
P321 Specific treatment (see on this label).
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**
- | | | |
|------------|---|----------------|
| HEALTH | 1 | Health = 1 |
| FIRE | 3 | Fire = 3 |
| REACTIVITY | 0 | 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.

(Contd. on page 3)

USA

Trade name: CLEARFIL Universal Bond

Wear fully protective suit.

(Contd. of page 2)

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Dilute with plenty of water.
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).
Ensure adequate ventilation.
- **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.
- **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a refrigerator (2-8 °C).
- **Information about storage in one common storage facility:**
Store away from oxidizing agents.
Store away from reducing agents.
- **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:**

64-17-5 ethanol

PEL	1900 mg/m ³ , 1000 ppm
REL	1900 mg/m ³ , 1000 ppm
TLV	Short-term value: 1880 mg/m ³ , 1000 ppm

- **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:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

(Contd. on page 4)

Trade name: CLEARFIL Universal Bond

(Contd. of page 3)

· 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	
· Appearance:	
Form:	Liquid
Color:	Yellow
· Odor:	Alcohol-like
· pH-value:	2.3
· Change in condition	
Melting point/Melting range:	-114.5 °C (ethanol)
Boiling point/Boiling range:	78 °C (ethanol)
· Flash point:	13 °C (ethanol)
· Flammability (solid, gaseous):	Not applicable.
· Ignition temperature:	425.0 °C (ethanol)
· Danger of explosion:	Product is not explosive. However, formation of explosive air/ vapor mixtures are possible.
· Explosion limits:	
Lower:	3.5 Vol % (ethanol)
Upper:	15.0 Vol % (ethanol)
· Vapor pressure:	59.0 hPa (20 °C, ethanol)
· Density:	1.1 g/cm ³
· Vapour density	1.6 g/cm ³ (ethanol, air=1)
· Evaporation rate	Not determined
· Solubility in / Miscibility with	
Water:	Partly miscible.

(Contd. on page 5)

Trade name: CLEARFIL Universal Bond

(Contd. of page 4)

- **Partition coefficient (n-octanol/water):** -0.32 (ethanol)
- **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)

64-17-5 ethanol

Oral	LD50	3450 mg/kg (mouse)
		7060 mg/kg (rat)
Inhalative	LC50/4 h	20000 mg/l (rat)
	LD50	3600 mg/kg (rat - intraperitoneal)

- **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.

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

(Contd. on page 6)

Trade name: CLEARFIL Universal Bond



(Contd. of page 5)

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.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· UN-Number	UN1170
· DOT, ADR, IMDG, IATA	UN1170
· UN proper shipping name	ETHANOL, mixture
· DOT	1170 ETHANOL (ETHYL ALCOHOL), mixture
· ADR	ETHANOL (ETHYL ALCOHOL)
· IMDG	ETHANOL
· IATA	ETHANOL
· Transport hazard class(es)	
· DOT	
	
· Class	3 Flammable liquids.
· Label	3
· ADR, IMDG, IATA	
	
· Class	3 Flammable liquids
· Label	3
· Packing group	II
· DOT, ADR, IMDG, IATA	II
· Environmental hazards:	No
· Marine pollutant:	No
· Special precautions for user	Warning: Flammable liquids
· Danger code (Kemler):	33
· EMS Number:	F-E,S-D
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	UN1170, ETHANOL (ETHYL ALCOHOL), mixture, 3, II

Trade name: CLEARFIL Universal Bond

(Contd. of page 6)

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:	64-17-5 ethanol
· Carcinogenity categories	
· EPA (Environmental Protection Agency)	None of the ingredients is listed.
· TLV (Threshold Limit Value established by ACGIH)	64-17-5 ethanol A3
· 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:** 1
- **Relevant phrases**
 - H225 Highly flammable liquid and vapour.
 - H315 Causes skin irritation.
 - H317 May cause an allergic skin reaction.
 - H319 Causes serious eye irritation.