

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### · 1.1 Product identifier

· **Trade name:** CLEARFIL TRI-S BOND PLUS (CLEARFIL S<sup>3</sup> BOND PLUS),  
 CLEARFIL TRI-S BOND PLUS Unit Dose (CLEARFIL S<sup>3</sup> BOND PLUS Unit Dose)

· **Article number:** 154-172

· **Registration number** Not applicable

### · 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

· **Application of the substance / the mixture** Dental bonding material

### · 1.3 Details of the supplier of the safety data sheet

#### · **Manufacturer:**

Kuraray Europe GmbH  
 Philipp-Reis-Str. 4,  
 65795 Hattersheim am Main  
 Germany  
 Phone: +49 (0)69 305 35 840  
 Fax: +49 (0)69 305 35 640  
 E-mail: dental@kuraray.de

#### · **Supplier:**

J & S Davis  
 5 Whitworth Road, Stevenage,  
 Hertfordshire, SG1 4QS  
 Great Britain  
 Tel: +44- (0) 1438 747344  
 Fax: +44- (0)1438 758909  
 E-mail: jsdsales@js-davis.co.uk

· **Further information obtainable from:** Manufacturer or Supplier

### · 1.4 Emergency telephone number:

National Poisons information Service (London Centre)  
 Guy's & St. Thomas' Hospital Trust  
 Medical Toxicology Unit  
 Avonley Road  
 LONDON  
 SE14 5ER  
 Emergency telephone: (local) 0870 600 6266 or +44 20 7771 5394  
 Administrative telephone: +44 20 7 771 53 10  
 Facsimile number: +44 20 7 771 53 09

## SECTION 2: Hazards identification

### · 2.1 Classification of the substance or mixture

· **Classification according to Regulation (EC) No 1272/2008**



GHS02 flame

Flam. Liq. 3 H226 Flammable liquid and vapour.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

(Contd. on page 2)

**Trade name: CLEARFIL TRI-S BOND PLUS (CLEARFIL S<sup>3</sup> BOND PLUS),  
CLEARFIL TRI-S BOND PLUS Unit Dose (CLEARFIL S<sup>3</sup> BOND PLUS Unit Dose)**

(Contd. of page 1)

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** GHS02, GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**  
2-hydroxyethyl methacrylate
- **Hazard statements**  
H226 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, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P241 Use explosion-proof electrical/ventilating/lighting/equipment.  
P303+P361+P353 IF ON SKIN (or hair): 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).  
P370+P378 In case of fire: Use for extinction: CO<sub>2</sub>, powder or water spray.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard-determining components of labelling:**  
bisphenol A diglycidylmethacrylate  
ethanol
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.1 Chemical characterisation: Substances** None
- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 1565-94-2 EINECS: 216-367-7	bisphenol A diglycidylmethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	15-35%
CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-35%
CAS: 64-17-5 EINECS: 200-578-6	ethanol ⚠ Flam. Liq. 2, H225	<20%

· **Other ingredients:**

Sodium fluoride  
10-Methacryloyloxydecyl dihydrogen phosphate  
Hydrophilic aliphatic dimethacrylate  
Hydrophobic aliphatic methacrylate  
Colloidal silica  
dl-Camphorquinone  
Initiators

(Contd. on page 3)

**Trade name: CLEARFIL TRI-S BOND PLUS (CLEARFIL S<sup>3</sup> BOND PLUS),  
CLEARFIL TRI-S BOND PLUS Unit Dose (CLEARFIL S<sup>3</sup> BOND PLUS Unit Dose)**

Accelerators  
Water

(Contd. of page 2)

## SECTION 4: First aid measures

### · 4.1 Description of 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; call for medical help immediately.

If symptoms persist consult doctor.

### · 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

### · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## SECTION 5: Firefighting measures

### · 5.1 Extinguishing media

#### · Suitable extinguishing agents:

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

### · 5.2 Special hazards arising from the substance or mixture

No further relevant information available.

### · 5.3 Advice for firefighters

#### · Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

## SECTION 6: Accidental release measures

### · 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

### · 6.2 Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

### · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Ensure adequate ventilation.

### · 6.4 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.

## SECTION 7: Handling and storage

### · 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

### · Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

(Contd. on page 4)

**Trade name: CLEARFIL TRI-S BOND PLUS (CLEARFIL S<sup>3</sup> BOND PLUS),  
CLEARFIL TRI-S BOND PLUS Unit Dose (CLEARFIL S<sup>3</sup> BOND PLUS Unit Dose)**

(Contd. of page 3)

Protect against electrostatic charges.

· **7.2 Conditions for safe storage, including any incompatibilities**

· **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 oxidising agents.

Store away from reducing agents.

· **Further information about storage conditions:**

Protect from heat and direct sunlight.

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

· **7.3 Specific end use(s)** No further relevant information available.

## SECTION 8: Exposure controls/personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

**64-17-5 ethanol**

WEL | Long-term value: 1920 mg/m<sup>3</sup>, 1000 ppm

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **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.

(Contd. on page 5)

**Trade name: CLEARFIL TRI-S BOND PLUS (CLEARFIL S<sup>3</sup> BOND PLUS),  
CLEARFIL TRI-S BOND PLUS Unit Dose (CLEARFIL S<sup>3</sup> BOND PLUS Unit Dose)**

(Contd. of page 4)

· Eye protection:



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

### · 9.1 Information on basic physical and chemical properties

#### · General Information

#### · Appearance:

· Form:	Liquid
· Colour:	Yellow
· Odour:	Alcohol-like

· pH-value: 2.3

#### · Change in condition

· Melting point/Melting range:	Not determined
· Boiling point/Boiling range:	Not determined

· Flash point: 34.5 °C

· Flammability (solid, gaseous): Flammable.

· Ignition temperature: Not determined

· Decomposition temperature: Not determined

· Danger of explosion: Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

#### · Explosion limits:

· Lower:	Not determined
· Upper:	Not determined

· Oxidising properties: Not determined

· Vapour pressure: Not determined

· Density:	1.1 g/cm <sup>3</sup>
· Relative density	Not determined
· Vapour density	Not determined
· Evaporation rate	Not determined

· Solubility in / Miscibility with water: Partly miscible.

· Partition coefficient (n-octanol/water): Not determined.

· Viscosity: Not determined

· 9.2 Other information: No further relevant information available.

## SECTION 10: Stability and reactivity

· 10.1 Reactivity: No further relevant information available.

· 10.2 Chemical stability

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· 10.3 Possibility of hazardous reactions: No dangerous reactions known.

· 10.4 Conditions to avoid: No further relevant information available.

(Contd. on page 6)

**Trade name: CLEARFIL TRI-S BOND PLUS (CLEARFIL S<sup>3</sup> BOND PLUS),  
CLEARFIL TRI-S BOND PLUS Unit Dose (CLEARFIL S<sup>3</sup> BOND PLUS Unit Dose)**

(Contd. of page 5)

- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

## SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

### · **LD/LC50 values 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:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

## SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

GB

(Contd. on page 7)


**Trade name: CLEARFIL TRI-S BOND PLUS (CLEARFIL S<sup>3</sup> BOND PLUS),  
CLEARFIL TRI-S BOND PLUS Unit Dose (CLEARFIL S<sup>3</sup> BOND PLUS Unit Dose)**

(Contd. of page 6)

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

· <b>14.1 UN-Number</b> · <b>ADR, IMDG, IATA</b>	UN1170
· <b>14.2 UN proper shipping name</b> · <b>ADR</b> · <b>IMDG</b> · <b>IATA</b>	1170 ETHANOL (ETHYL ALCOHOL), mixture ETHANOL (ETHYL ALCOHOL), mixture ETHANOL, mixture
· <b>14.3 Transport hazard class(es)</b> · <b>ADR, IMDG, IATA</b>	
· <b>Class</b> · <b>Label</b>	3 Flammable liquids. 3
· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	III
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b> · <b>Danger code (Kemler):</b> · <b>EMS Number:</b>	Warning: Flammable liquids. 30 F-E,S-D
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b> · <b>Limited quantities (LQ)</b> · <b>Transport category</b> · <b>Tunnel restriction code</b>	5L 3 D/E
· <b>UN "Model Regulation":</b>	UN1170, ETHANOL (ETHYL ALCOHOL), mixture, 3, III

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

(Contd. on page 8)

**Trade name: CLEARFIL TRI-S BOND PLUS (CLEARFIL S<sup>3</sup> BOND PLUS),  
CLEARFIL TRI-S BOND PLUS Unit Dose (CLEARFIL S<sup>3</sup> BOND PLUS Unit Dose)**

(Contd. of page 7)

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## SECTION 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.

· **Relevant phrases**

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

· **Abbreviations and acronyms:**

Flam. Liq. 2: Flammable liquids – Category 2

Flam. Liq. 3: Flammable liquids – Category 3

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

· **\* Data compared to the previous version altered.**