

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

1.1 Product identifier

· **Trade name:** CLEARFIL CERAMIC PRIMER PLUS

· **Article number:** 215

· **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** Adhesive, dental ceramic/ Adhesive, dental metal

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. 2 H225 Highly flammable liquid and vapour.

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

· **Signal word** Danger

· **Hazard statements**

H225 Highly flammable liquid and vapour.

· **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.

(Contd. on page 2)

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 1)

- P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P240 Ground/bond container and receiving equipment.
 P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P370+P378 In case of fire: Use for extinction: CO₂, 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:**

- ethanol
 3-trimethoxysilylpropyl methacrylate

· **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: 64-17-5	ethanol	>80%
EINECS: 200-578-6	⚠ Flam. Liq. 2, H225	
CAS: 2530-85-0	3-trimethoxysilylpropyl methacrylate	< 5%
EINECS: 219-785-8	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

- **Other ingredients:** 10-Methacryloyloxydecyl dihydrogen phosphate

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
 · **After inhalation:** Supply fresh air; consult doctor in case of complaints.
 · **After skin contact:** Immediately rinse with water.
 · **After eye contact:** Rinse opened eye for several minutes under running water. Then 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:**
 CO₂, 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.

(Contd. on page 3)

Trade name: CLEARFIL CERAMIC PRIMER PLUS

Wear fully protective suit.

(Contd. of page 2)

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.

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

Keep ignition sources away - Do not smoke.

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:**

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

· **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/m³, 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:** Wash hands before breaks and at the end of work.

· **Respiratory protection:** Not required.

· **Protection of hands:**

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.

(Contd. on page 4)

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 3)

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

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

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

· **pH-value:** Not determined

· **Change in condition**

· Melting point/Melting range:	-114.5 °C (ethanol)
· Boiling point/Boiling range:	78 °C (ethanol)

· **Flash point:** 13 °C (ethanol)

· **Ignition temperature:** 425.0 °C (ethanol)

· **Decomposition temperature:** Not determined

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

· **Explosion limits:**

· Lower:	3.5 Vol % (ethanol)
· Upper:	15.0 Vol % (ethanol)

· **Oxidising properties** Not determined

· **Vapour pressure:** 59.0 hPa (20 °C, ethanol)

· Density:	0.8 g/cm ³
· Relative density	Not determined
· Vapour density	1.6 g/cm ³ (ethanol, air=1)
· Evaporation rate	Not determined

· **Solubility in / Miscibility with water:** Partly miscible.

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

· **Viscosity:** Not determined

(Contd. on page 5)

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 4)

· **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.
- **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:**

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)

2530-85-0 3-trimethoxysilylpropyl methacrylate

Oral	LD50	22600 mg/kg (rat)
Dermal	LD50	500 mg/kg (rabbit)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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.

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

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Trade name: CLEARFIL CERAMIC PRIMER PLUS

· **12.6 Other adverse effects** No further relevant information available. (Contd. of page 5)

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

SECTION 14: Transport information

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

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

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(Contd. on page 7)

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 6)

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.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.

· Abbreviations and acronyms:

- Flam. Liq. 2: Flammable liquids – Category 2
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· * Data compared to the previous version altered.