


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**
- **Supplier :**
Kuraray Europe GmbH
Philipp-Reis-Str. 4,
65795 Hattersheim am Main
Germany
Phone: +49 (0)69 305 35 835
E-mail: dental.eu@kuraray.com
- **Further information obtainable from:** Supplier
- **1.4 Emergency telephone number:**
(UK) 0 800 680 0425
(GB) +44 20 35147487
(AU) +61 2 80363166
* 3E Company
* Kuraray Access Code:334674

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Regulation (EC) No 1272/2008**
Flam. Liq. 2 H225 Highly flammable liquid and vapour.
 - **Additional information**
Medical devices as defined in Regulation (EU) 2017/745 and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (GB CLP/ GHS) usually if they are in the finished state and intended for the final user.
 - **Additional information:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (GB CLP/GHS) usually if they are in the finished state and intended for the final user.

 - **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
 - **Hazard pictograms**
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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. |
| P233 | Keep container tightly closed. |
| P240 | Ground and bond container and receiving equipment. |
| P241 | Use explosion-proof [electrical/ventilating/lighting] equipment. |
| P242 | Use non-sparking tools. |

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P243 Take action to prevent static discharges.
 P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
 P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
 P403+P235 Store in a well-ventilated place. Keep cool.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.


- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

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

· **Dangerous components:**

CAS: 64-17-5	ethanol		>80%
EINECS: 200-578-6			

- **Other ingredients:**
- 3-Trimethoxysilylpropyl methacrylate
- 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.
 Wear fully protective suit.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** See Section 8.

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- **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

· 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 ³ , 1000 ppm
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- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see item 7.
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Hand protection**
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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Safety data sheet

according to 1907/2006/EC, Article 31

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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/face protection** Safety glasses

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

- | | |
|---|--|
| · Physical state | Liquid |
| · Colour: | Colourless |
| · Odour: | Alcohol-like |
| · Melting point/freezing point: | -114.5 °C (ethanol) |
| · Boiling point or initial boiling point and boiling range | 78 °C (ethanol) |
| · Flammability | Flammable. |
| · Lower and upper explosion limit | |
| · Lower: | 3.5 Vol % (ethanol) |
| · Upper: | 15.0 Vol % (ethanol) |
| · Flash point: | 13 °C (ethanol) |
| · Auto-ignition temperature: | 425.0 °C (ethanol) |
| · Decomposition temperature: | Not determined |
| · pH | Not determined |
| · Viscosity: | Not determined |
| · Kinematic viscosity | Not determined. |
| · Solubility | |
| · water: | Partly miscible. |
| · Partition coefficient n-octanol/water (log value) | -0.32 (ethanol) |
| · Vapour pressure: | 59.0 hPa (20°C, ethanol) |
| · Density and/or relative density | |
| · Density: | 0.8 g/cm ³ |
| · Relative density | Not determined |
| · Relative vapour density | 1.6 g/cm ³ (ethanol, air=1) |

· 9.2 Other information

- | | |
|--|---|
| · Appearance: | |
| · Form: | Liquid |
| · Important information on protection of health and environment, and on safety. | |
| · Explosive properties: | Product is not explosive. However, formation of explosive air/vapour mixtures are possible. |
| · Change in condition | |
| · Softening point/range | |
| · Oxidising properties | Not determined |
| · Evaporation rate | Not determined |
| · Oxidising gases | Void |
| · Gases under pressure | Void |
| · Flammable liquids | |
| Highly flammable liquid and vapour. | |
| · Flammable solids | Void |
| · Self-reactive substances and mixtures | Void |
| · Pyrophoric liquids | Void |
| · Pyrophoric solids | Void |
| · Self-heating substances and mixtures | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |

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· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **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	22,600 mg/kg (rat)
Dermal	LD50	500 mg/kg (rabbit)

- **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.
- **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.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

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.

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- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **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.

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 or ID number	
· ADR, IMDG, IATA	1170
· 14.2 UN proper shipping name	
· ADR	1170 ETHANOL (ETHYL ALCOHOL), mixture
· 14.3 Transport hazard class(es)	
· ADR, IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	3
· 14.4 Packing group	
· ADR, IMDG, IATA	II
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Hazard identification number (Kemler code):	33
· EMS Number:	F-E,S-D
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· UN "Model Regulation":	UN1170; ETHANOL (ETHYL ALCOHOL), mixture; 3; II

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SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 94/33/EC:** Care should be taken when people under 18 handle this product.
- **Directive 94/85/EEC:** No further relevant information available.
- **Chemical safety assessment**
- **Named dangerous substances - ANNEX I** None of the ingredient is listed.
- **Seveso category** FLAMMABLE LIQUIDS
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t
- **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.
- **Abbreviations and acronyms:**
ELINCS: European List of Notified Chemical Substances
Flam. Liq. 2: Flammable liquids – Category 2
- *** Data compared to the previous version altered.**