

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** Dental materials

· 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:

[Malta] National poisons helpline; 1774 to the public from Monday to Sunday between 8:00 and 20:00
[3E Company] (Great Britain (London))+44 20 351 47487, (United Kingdom - Domestic)+44 800 680 0425,
(United Kingdom - International)+44 808 189 0979 (Europe Non-Specific)+1 760 476 3962 *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.

· 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.

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.

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.

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

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 64-17-5	ethanol	 Flam. Liq. 2, H225	80-100%
EINECS: 200-578-6			

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **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.
- **After swallowing:** 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.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
See Section 8.
- **6.2 Environmental precautions:**
Prevent seepage into sewage system, workpits and cellars.
Before cleaning, pre-clean the equipment under running water with a damp cloth.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
Absorb liquid components with liquid-binding material.
Vacuum or sweep material and place in a disposal container. Provide ventilation.
Use appropriate Personal Protective Equipment (PPE).
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.

· 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:** Not required

· 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:

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 valid during the making were used as basis.

· 8.2 Exposure controls

· **Appropriate engineering controls** No further data; see section 7.

· 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.

· **Respiratory protection:** Suitable respiratory protective device recommended.

· Hand protection



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.

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· Eye/face protection



Tightly sealed goggles

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:	Not determined.
· Boiling point or initial boiling point and boiling range	78 °C (64-17-5 ethanol)
· Flammability	Highly flammable.
· Lower and upper explosion limit	
· Lower:	3.5 Vol % (64-17-5 ethanol)
· Upper:	15 Vol % (64-17-5 ethanol)
· Flash point:	13 °C (64-17-5 ethanol)
· Auto-ignition temperature:	425 °C (64-17-5 ethanol)
· Decomposition temperature:	Not applicable.
· pH	Not determined
· Kinematic viscosity	Not determined
· Solubility	
· water:	Partly miscible.
· Partition coefficient n-octanol/water (log value)	Not applicable.
· Vapour pressure at 20 °C:	59 hPa (64-17-5 ethanol)
· Density at 20 °C:	0.8 g/cm ³
· Relative vapour density	Not determined
· Particle characteristics	Not applicable.

· 9.2 Other information

· Information with regard to physical hazard classes

· Explosives	Product does not present an explosion hazard.
· Flammable gases	Void
· Aerosols	Void
· 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
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void

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· Desensitised explosives	Void
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SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** No hazardous reaction when handled and stored according to provisions.
- **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:**
- **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
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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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable
- **vPvB:** Not applicable
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **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**
Dispose of this product as medical waste.

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Mix residues on disposable materials (e.g. paper, tray) and dispose of them as solid waste.

· Uncleaned packaging:
· Recommendation:

Dispose of packaging according to regulations on the disposal of packagings.

Non contaminated packagings may be recycled.

Do not rinse product containers before disposal.

SECTION 14: Transport information
· 14.1 UN number or ID number
· ADR, IMDG, IATA UN1170

· 14.2 UN proper shipping name
· ADR 1170 ETHANOL (ETHYL ALCOHOL) mixture
· IMDG ETHANOL (ETHYL ALCOHOL) mixture
· IATA ETHANOL 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: Not applicable

· 14.6 Special precautions for user
· Hazard identification number (Kemler code): Warning: Flammable liquids.
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· EMS Number: F-E,S-D
· Stowage Category A

· 14.7 Maritime transport in bulk according to IMO instruments

Not applicable

· Transport/Additional information:
· ADR
· Limited quantities (LQ) 1L
· Excepted quantities (EQ) Code: E2
 Maximum net quantity per inner packaging: 30 ml
 Maximum net quantity per outer packaging: 500 ml
· Transport category 2
· Tunnel restriction code D/E

· IMDG
· Limited quantities (LQ) 1L
· Excepted quantities (EQ) Code: E2
 Maximum net quantity per inner packaging: 30 ml
 Maximum net quantity per outer packaging: 500 ml

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· UN "Model Regulation":	UN 1170 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.
- **Named dangerous substances - ANNEX I** None of the ingredient is listed.
- **Seveso category P5c** 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

· **REGULATION (EU) 2019/1021 on persistent organic pollutants (POP)**

None of the ingredients is listed.

· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **Regulation (EU) No 649/2012**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **REGULATION (EU) 2024/590 on substances that deplete the ozone layer**

None of the ingredients is listed.

- **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.

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 (CLP/GHS) usually if they are in the finished state and intended for the final user.

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

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

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

· **Abbreviations and acronyms:**

ELINCS: European List of Notified Chemical Substances

Flam. Liq. 2: Flammable liquids – Category 2

· **Relevant phrases**

H225 Highly flammable liquid and vapour.