


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

- **1.1 Product identifier**
- **Trade name:** CLEARFIL SA PRIMER
- **Article number:** 079
- **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 material for tooth surface conditioning
- **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.

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  - **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.  |
| P243 | Take action to prevent static discharges.  |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  |

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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.

### 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	 Flam. Liq. 2, H225	70-90%
EINECS: 200-578-6			

· **Other ingredients:**

Water  
N-Methacryloyl-5-aminosalicylic acid

### 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:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **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** See Section 8.
- **6.2 Environmental precautions:**  
Dilute with plenty of water.  
Do not allow to enter sewers/ surface or ground water.

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

Printing date 13.02.2023

Version number 7 (replaces version 6)

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- **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 <sup>3</sup> , 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.
- **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** Safety glasses

## SECTION 9: Physical and chemical properties

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

#### · General Information

· Physical state	Liquid
· Colour:	Transparent
· Odour:	Odourless
· 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 applicable.
· Viscosity:	Not determined
· Kinematic viscosity	Not applicable.
· Solubility	
· water:	Fully 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:	1.1 g/cm <sup>3</sup>
· Relative density	Not determined
· Relative vapour density	1.6 g/cm <sup>3</sup> (ethanol, air=1)
· Relative vapour density	Ikke bestemt

### · 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
· Oxidising liquids	Void
· Oxidising solids	Void

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- |                                  |      |
|----------------------------------|------|
| · <b>Organic peroxides</b>       | Void |
| · <b>Corrosive to metals</b>     | Void |
| · <b>Desensitised explosives</b> | 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)

- **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.
- **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.

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- **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**

· <b>14.1 UN number or ID number</b> · <b>ADR, IMDG, IATA</b>	1170
· <b>14.2 UN proper shipping name</b>	1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
· <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>	II
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b> · <b>Hazard identification number (Kemler code):</b> · <b>EMS Number:</b>	Warning: Flammable liquids. 33 F-E,S-D
· <b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable.
· <b>UN "Model Regulation":</b>	UN1170; ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION); 3; II

**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.

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- 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
- Regulation (EU) No 649/2012

· **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.

- **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.**