


**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 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:**  
[United Kingdom] Only for NHS and other healthcare professionals; UK National Poisons Information Service (NPIS): +44 (0)344 892 0111 Ireland NPIC: +353 (0)1 809 2566  
For members of Public; NHS 111 in England: 111, NHS 24 in Scotland: 111, NHS Direct in Wales: 111 or 0845 4647, Ireland NPIC: +353 (0)1 809 2166(8 am to 10 pm)  
[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 GB 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]. |

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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

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

#### · Dangerous components:

CAS: 64-17-5	ethanol	 Flam. Liq. 2, H225	65-85%
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:**  
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.

### 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).

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- **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.
- 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:** No special requirements.
- **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:**
- |                     |  |
|---------------------|--|
| 64-17-5 ethanol     |  |
| WEL (Great Britain) | 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**
  - **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.

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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**



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

· <b>General Information</b>	
· <b>Physical state</b>	Liquid
· <b>Colour:</b>	Colourless
· <b>Odour:</b>	Alcohol-like
· <b>Melting point/freezing point:</b>	Not determined.
· <b>Boiling point or initial boiling point and boiling range</b>	78 °C (64-17-5 ethanol)
· <b>Flammability</b>	Highly flammable.
· <b>Lower and upper explosion limit</b>	
· <b>Lower:</b>	3.5 Vol % (64-17-5 ethanol)
· <b>Upper:</b>	15 Vol % (64-17-5 ethanol)
· <b>Flash point:</b>	13 °C (64-17-5 ethanol)
· <b>Auto-ignition temperature:</b>	425 °C (64-17-5 ethanol)
· <b>Decomposition temperature:</b>	Not applicable.
· <b>pH</b>	Not determined
· <b>Kinematic viscosity</b>	Not determined
· <b>Solubility</b>	
· <b>water:</b>	Fully miscible.
· <b>Partition coefficient n-octanol/water (log value)</b>	Not applicable.
· <b>Vapour pressure at 20 °C:</b>	59 hPa (64-17-5 ethanol)
· <b>Density at 20 °C:</b>	1.1 g/cm <sup>3</sup>
· <b>Relative vapour density</b>	Not determined
· <b>Particle characteristics</b>	Not applicable.

### 9.2 Other information

#### Information with regard to physical hazard classes

· <b>Explosives</b>	Product does not present an explosion hazard.
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Highly flammable liquid and vapour.
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void

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· Desensitised explosives

Void

**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**

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.  
 Uncured product residues should be cured before disposal if possible.

**· 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.  
 33  
**· 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**
**· Tunnel restriction code** 2  
 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**· **Regulated explosives precursors**

None of the ingredients is listed.

· **Regulated poisons**

None of the ingredients is listed.

· **Reportable explosives precursors**

None of the ingredients is listed.

· **Reportable poisons**

None of the ingredients is listed.

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

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

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**· 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.

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

GB