


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

- **1.1 Product identifier**
- **Trade name:** CLEARFIL DC Activator
- **Article number:** 196
- **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**
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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. |
| 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	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).

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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:** 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:**
- | | |
|------------------------|--|
| 64-17-5 ethanol | |
| WEL (Great Britain) | Long-term value: 1920 mg/m ³ , 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

· 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:	Fully 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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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**· **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