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according to 1907/2006/EC, Article 31

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

· **1.1 Product identifier**

· **Trade name: CLEARFIL NEW BOND ; UNIVERSAL**

· **Article number:** 022-U
· **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 bonding material

· **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

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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.

· **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.

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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

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

· **Dangerous components:**

CAS: 64-17-5 EINECS: 200-578-6	ethanol	Flam. Liq. 2, H225	>90%

· **Other ingredients:**
Catalyst
Accelerator

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.
If symptoms persist, 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.
· **6.2 Environmental precautions:**
Dilute with plenty of water.

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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.

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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/m³, 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 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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· **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

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	Liquid
· **Colour:**	Transparent
· **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℃ (ethanol)
· **Auto-ignition temperature:**	425.0 °C (ethanol)
· **Decomposition temperature:**	Not determined.
· **pH**	Not determined.
· **Viscosity:**	Not determined
· **Kinematic viscosity**	Not determined.
· **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:**	0.79 g/cm3
· **Relative density**	Not determined.
· **Relative vapour density**	1.6 g/cm³ (ethanol, air=1)
· **Relative vapour density**	Not determined

· **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

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· **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
· **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 - intraperioneal)

· **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.

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· **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**
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**	1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
· **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 SOLUTION (ETHYL ALCOHOL SOLUTION); 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.

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· **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
· **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.**