

*** SECTION 1: Identification of the substance/mixture and of the company/undertaking****· 1.1 Product identifier**

· **Trade name:** CLEARFIL Universal Bond Quick

· **Article number:** 219

· **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)+44 20 35147487 (United Kingdom)800 680 0425 (UK English)+44 8 08 189 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. 3 H226 Flammable liquid and vapour.

Skin Sens. 1 H317 May cause an allergic skin reaction.

· 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 GHS07

· Signal word Warning**· Hazard-determining components of labelling:**

2-hydroxyethyl methacrylate

phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide

· Hazard statements

H226 Flammable liquid and vapour.

H317 May cause an allergic skin reaction.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

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P240 Ground and bond container and receiving equipment.
P241 Use explosion-proof [electrical/ventilating/lighting] equipment.
P242 Use non-sparking tools.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
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.

· 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	10 - 30%
EINECS: 200-578-6	Flam. Liq. 2, H225	
CAS: 868-77-9	2-hydroxyethyl methacrylate	3 - 10%
EINECS: 212-782-2	! Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	0.1 - 1%
ELINCS: 423-340-5	! Skin Sens. 1A, H317; Aquatic Chronic 4, H413	

- **Additional information:** Silicon oxide; Nanoform, Silanated amorphous silica, particle size 1 - 100 nm

*** 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 and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

- **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.

- **For safety reasons unsuitable extinguishing agents:** Water with full jet

- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

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- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

*	SECTION 6: Accidental release measures		
	<ul style="list-style-type: none">· 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.· 6.3 Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to section 13. Ensure adequate ventilation. Contain spill, then place in a suitable container. Minimize dust generation. Do not flush to sewer or allow to enter waterways. 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. See Section 13 for disposal information.		
*	SECTION 7: Handling and storage		
	<ul style="list-style-type: none">· 7.1 Precautions for safe handling Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols. 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<ul style="list-style-type: none">· 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		
	<ul style="list-style-type: none">· 8.1 Control parameters· Ingredients with limit values that require monitoring at the workplace:<table border="1"><tr><td>64-17-5 ethanol</td></tr><tr><td>WEL (Great Britain) Long-term value: 1920 mg/m³, 1000 ppm</td></tr></table>· 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.	64-17-5 ethanol	WEL (Great Britain) Long-term value: 1920 mg/m ³ , 1000 ppm
64-17-5 ethanol			
WEL (Great Britain) Long-term value: 1920 mg/m ³ , 1000 ppm			

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· 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.

· 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:

Yellow

· 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

Flammable.

· Lower and upper explosion limit

3.5 Vol % (64-17-5 ethanol)

· Lower:

15 Vol % (64-17-5 ethanol)

· Upper:

36 °C

· Flash point:

256 °C (Hydrophilic amide monomer)

· Auto-ignition temperature:

Not applicable.

· Decomposition temperature:

2.3

· pH at 20 °C

Not determined.

· Kinematic viscosity

Partly miscible.

· Solubility

Not applicable.

· water:

59 hPa (64-17-5 ethanol)

· Partition coefficient n-octanol/water (log value)1.1 g/cm³**· Vapour pressure at 20 °C:**

Not determined.

· Density at 20 °C:

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· 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	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
· 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

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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:**868-77-9 2-hydroxyethyl methacrylate**

Oral	LD50	4,680 mg/kg (guinea pig)
		3,275 mg/kg (mouse)
		5,050 mg/kg (rat)
Dermal	LD50	5,000 mg/kg (rabbit)

- **Primary irritant effect:**
- **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** May cause an allergic skin reaction.
- **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.

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· 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** For information on endocrine disrupting properties see section 11.**· 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:** Dispose of packaging according to regulations on the disposal of packagings.**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**

III

· 14.5 Environmental hazards:

Not applicable.

· 14.6 Special precautions for user

Warning: Flammable liquids.

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· Hazard identification number (Kemler code):	30
· 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)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· Transport category	3
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 1170 ETHANOL (ETHYL ALCOHOL) MIXTURE, 3, III

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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

7681-49-4 sodium fluoride

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) No 649/2012

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 (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone-depleting potential)

None of the ingredients is listed.

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- **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.

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

- **Relevant phrases**

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H413 May cause long lasting harmful effects to aquatic life.

- **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

Flam. Liq. 3: Flammable liquids – Category 3

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1A: Skin sensitisation – Category 1A

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

- *** Data compared to the previous version altered.**

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