

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

- **1.1 Product identifier**
- **Trade name:** CLEARFIL FII ; UNIVERSAL PASTE
- **Article number:** 109-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 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**  
The product is not classified, according to the GB CLP regulation.
- **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** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional Information**  
EUH210 Safety data sheet available on request.
- **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:**  
This mixture does not contain any substances to be mentioned according to the criteria of Regulation (EC) No 1272/2008.
- **Dangerous components:** Void

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

### 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:** 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.  
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** See Section 8.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
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

- **7.1 Precautions for safe handling**  
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:** No special measures required.
- **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.  
Protect from heat and direct sunlight.  
Store in cool, dry conditions in well sealed receptacles.

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**Safety data sheet  
according to UK REACH**

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· **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:****14808-60-7 Quartz (SiO<sub>2</sub>)**

|            |                                                                 |
|------------|-----------------------------------------------------------------|
| BOELV (EU) | Long-term value: 0.1* mg/m <sup>3</sup><br>*respirable fraction |
|------------|-----------------------------------------------------------------|

· **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:** Wash hands before breaks and at the end of work.· **Respiratory protection:** Suitable respiratory protective device recommended.· **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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye/face protection** Safety glasses**SECTION 9: Physical and chemical properties**· **9.1 Information on basic physical and chemical properties**· **General Information**

|                                                                   |                 |
|-------------------------------------------------------------------|-----------------|
| · <b>Physical state</b>                                           | Solid           |
| · <b>Colour:</b>                                                  | Orange          |
| · <b>Odour:</b>                                                   | Odourless       |
| · <b>Melting point/freezing point:</b>                            | Not determined. |
| · <b>Boiling point or initial boiling point and boiling range</b> | Not determined. |
| · <b>Flammability</b>                                             | Not determined. |
| · <b>Lower and upper explosion limit</b>                          |                 |
| · <b>Lower:</b>                                                   | Not applicable. |
| · <b>Upper:</b>                                                   | Not applicable. |
| · <b>Flash point:</b>                                             | Not applicable  |
| · <b>Auto-ignition temperature:</b>                               | Not applicable. |
| · <b>Decomposition temperature:</b>                               | Not applicable. |
| · <b>pH</b>                                                       | Not determined. |
| · <b>Kinematic viscosity</b>                                      | Not applicable. |
| · <b>Solubility</b>                                               |                 |
| · <b>water:</b>                                                   | Insoluble.      |
| · <b>Partition coefficient n-octanol/water (log value)</b>        | Not applicable. |

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|                            |                       |
|----------------------------|-----------------------|
| · Vapour pressure:         | Not applicable.       |
| · Density at 20 °C:        | 2.2 g/cm <sup>3</sup> |
| · Relative vapour density  | Not applicable.       |
| · Particle characteristics | See Section 3.        |

### · 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                                                         | Void                                          |
| · 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.
- **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.

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### 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:** Not hazardous for water.

### 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

- |                                                                       |                 |
|-----------------------------------------------------------------------|-----------------|
| · <b>14.1 UN number or ID number</b>                                  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                         | Void            |
| · <b>14.2 UN proper shipping name</b>                                 |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                         | Void            |
| · <b>14.3 Transport hazard class(es)</b>                              |                 |
| · <b>ADR, IMDG, IATA</b>                                              |                 |
| · <b>Class</b>                                                        | Void            |
| · <b>14.4 Packing group</b>                                           |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                         | Void            |
| · <b>14.5 Environmental hazards:</b>                                  | Not applicable. |
| · <b>14.6 Special precautions for user</b>                            | Not applicable. |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                       | Void            |

### 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.

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· **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.· **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.

· **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.

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