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SECTION 1: Identification of the substance/mixture and of the company/undertaking**· 1.1 Product identifier****· Trade name: CLEARFIL FII ; CATALYST PASTE****· Article number: 109-C****· 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

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SECTION 2: Hazards identification**· 2.1 Classification of the substance or mixture****· Classification according to Regulation (EC) No 1272/2008**

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

GHS07

· Signal word Warning**· Hazard-determining components of labelling:**Triethyleneglycol dimethacrylate
benzoyl peroxide**· Hazard statements**

H317 May cause an allergic skin reaction.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

P302+P352 IF ON SKIN: Wash with plenty of water.

P362+P364 Take off contaminated clothing and wash it before reuse.

(Contd. on page 2)

GB

Trade name: CLEARFIL FII ; CATALYST PASTE

(Contd. of page 1)

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
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: 109-16-0	Triethyleneglycol dimethacrylate	< 10%
EINECS: 203-652-6	⚠ Skin Sens. 1B, H317	
CAS: 94-36-0	benzoyl peroxide	< 3%
EINECS: 202-327-6	⚠ ⚡ Org. Perox. B, H241; ⚡ Eye Irrit. 2, H319; Skin Sens. 1, H317	

- **Additional information:** Silicon oxide; Nanoform, 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****5.2 Suitable extinguishing agents:**

CO₂, 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:

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

(Contd. on page 3)

GB

Trade name: CLEARFIL FII ; CATALYST PASTE

(Contd. of page 2)

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**

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: 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.

· 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 (SiO₂)**

BOELV (EU)	Long-term value: 0.1* mg/m ³
*respirable fraction	

94-36-0 benzoyl peroxide

WEL (Great Britain)	Long-term value: 5 mg/m ³
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· 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.

(Contd. on page 4)

GB

Trade name: CLEARFIL FII ; CATALYST PASTE

(Contd. of page 3)

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 Safety glasses**SECTION 9: Physical and chemical properties****· 9.1 Information on basic physical and chemical properties****· General Information****· Physical state**

Solid

· Colour:

White

· Odour:

Odourless

· Melting point/freezing point:

Not determined.

· Boiling point or initial boiling point and boiling range

Not determined.

· Flammability

Not determined.

· Lower and upper explosion limit**· Lower:**

Not applicable.

· Upper:

Not applicable.

· Flash point:

Not applicable

· Auto-ignition temperature:

Not applicable.

· Decomposition temperature:

Not applicable.

· pH

Not determined.

· Kinematic viscosity

Not applicable.

· Solubility

Not applicable.

· water:

Insoluble.

· Partition coefficient n-octanol/water (log value)

Not applicable.

· Vapour pressure:

Not applicable.

· Density at 20 °C:2.2 g/cm³**· 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

(Contd. on page 5)

GB

Trade name: CLEARFIL FII ; CATALYST PASTE

(Contd. of page 4)

· 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** 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:**

- 109-16-0 Triethyleneglycol dimethacrylate

Oral	LD50	2,000 mg/kg (mouse)
		10,800 mg/kg (rat)

- **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.

- **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.

(Contd. on page 6)

GB

Trade name: CLEARFIL FII ; CATALYST PASTE

(Contd. of page 5)

- **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

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

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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.
- **Regulation (EU) No 649/2012**
None of the ingredients is listed.

(Contd. on page 7)

GB

Trade name: CLEARFIL FII ; CATALYST PASTE

(Contd. of page 6)

· 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.

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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

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

· 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

Org. Perox. B: Organic peroxides – Type B

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

Skin Sens. 1: Skin sensitisation – Category 1

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

· * Data compared to the previous version altered.

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