

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

- **1.1 Product identifier**
- **Trade name:** CLEARFIL DC CORE PLUS ; A & B Paste
- **Article number:** 162
- **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** Core build-up 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

## 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.

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- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Labelling of packages where the contents do not exceed 125 ml**
- **Precautionary statements**  
EUH208: Contains benzoyl peroxide. May produce an allergic reaction.  
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:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 1565-94-2	bisphenol A diglycidylmethacrylate	<5%
EINECS: 216-367-7	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	

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CAS: 1344-28-1 EINECS: 215-691-6	aluminium oxide substance with a Community workplace exposure limit	<5%
CAS: 109-16-0 EINECS: 203-652-6	Triethyleneglycol dimethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	<4%
CAS: 94-36-0 EINECS: 202-327-6	benzoyl peroxide ⚠ Self-react. B, H241; Org. Perox. B, H241; ⚠ Eye Irrit. 2, H319; Skin Sens. 1, H317	<1%

· **Other ingredients:**

Silanated barium glass filler  
Hydrophobic aromatic dimethacrylate  
Hydrophilic aliphatic dimethacrylate  
Hydrophobic aliphatic dimethacrylate  
Silanated amorphous silica  
Amorphous silica  
Accelerators  
dl-Camphorquinone  
Initiators  
Pigments

· **Additional information:**

Silicon oxide; Nanoform, Amorphous silica and Silanated amorphous silica, particle size 1 - 100 nm  
Aluminium oxide; Nanoform, particle size 1 - 100 nm

## SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **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:** Generally the product does not irritate the skin.

· **After eye contact:** Rinse opened eye for several minutes under running water.

· **After swallowing:** Do not induce vomiting; call for medical help immediately.

· **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.

· **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:** No special measures required.

· **6.3 Methods and material for containment and cleaning up:**

Pick up mechanically. Ensure adequate ventilation.

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- **6.4 Reference to other sections** No dangerous substances are released.

## SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Ensure good ventilation/exhaustion at the workplace.
- **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:**  
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.

## SECTION 8: Exposure controls/personal protection

### · 8.1 Control parameters

- **Ingredients with limit values that require monitoring at the workplace:**

#### 1344-28-1 aluminium oxide

WEL	Long-term value: 10* 4** mg/m <sup>3</sup> *inhalable dust **respirable dust
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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 item 7.
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **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.
- **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** Goggles recommended during refilling

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## SECTION 9: Physical and chemical properties

### · 9.1 Information on basic physical and chemical properties

#### · General Information

· Physical state	Solid
· Colour:	According to product specification
· Odour:	Slightly methacrylate odour
· 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 determined.
· Upper:	Not determined.
· Flash point:	Not determined.
· Auto-ignition temperature:	Not determined
· Decomposition temperature:	Not determined
· pH	Not determined.
· Viscosity:	Not determined
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density:	2.0 g/cm <sup>3</sup>
· Relative density	Not determined
· Relative vapour density	Not determined.
· Particle characteristics	See item 3.

### · 9.2 Other information

· Appearance:	
· Form:	Pasty
· Important information on protection of health and environment, and on safety.	
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Softening point/range	
· Oxidising properties	Not determined
· Evaporation rate	Not determined
· 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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**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 07.04.2023

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**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.
- **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.
- **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** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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### 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, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	Void
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <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**
- **Directive 94/33/EC:** Care should be taken when people under 18 handle this product.
- **Directive 94/85/EEC:** No further relevant information available.
- **Chemical safety assessment**
- **Named dangerous substances - ANNEX I** None of the ingredient 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**
- H241 Heating may cause a fire or explosion.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- **Abbreviations and acronyms:**
- ELINCS: European List of Notified Chemical Substances
- Self-react. B: Self-reactive substances and mixtures – Type B
- Org. Perox. B: Organic peroxides – Type B
- 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
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- **\* Data compared to the previous version altered.**