


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

- **1.1 Product identifier**
- **Trade name:** CLEARFIL NEW BOND ; CATALYST
- **Article number:** 022-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 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

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
  - **Classification according to Regulation (EC) No 1272/2008**  
Skin Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 2 H319 Causes serious eye irritation.  
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:**  
2-hydroxyethyl methacrylate  
benzoyl peroxide
  - **Hazard statements**  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H317 May cause an allergic skin reaction.
  - **Precautionary statements**  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P264 Wash thoroughly after handling.

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- P280 Wear protective gloves / eye protection / face protection.  
 P302+P352 IF ON SKIN: Wash with plenty of water.  
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P362+P364 Take off contaminated clothing and wash it before reuse.  
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
 P321 Specific treatment (see on this label).  
 P337+P313 If eye irritation persists: Get medical advice/attention.  
 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: 1565-94-2 EINECS: 216-367-7	bisphenol A diglycidylmethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	20-40%
CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	20-40%
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	<3%

- **Other ingredients:**  
 Hydrophobic aliphatic dimethacrylate  
 10-Methacryloyloxydecyl dihydrogen phosphate

**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:** Immediately wash with water and soap and rinse thoroughly.
- **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:**  
 CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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- **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:** 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.  
Prevent formation of aerosols.
- **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:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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:**  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **Respiratory protection:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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· **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 through 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**

· <b>Physical state</b>	Liquid
· <b>Colour:</b>	Transparent
· <b>Odour:</b>	Odourless
· <b>Melting point/freezing point:</b>	-12 °C (2-hydroxyethyl methacrylate)
· <b>Boiling point or initial boiling point and boiling range</b>	205 °C (2-hydroxyethyl methacrylate)
· <b>Flammability</b>	Not determined.
· <b>Lower and upper explosion limit</b>	
· <b>Lower:</b>	Not determined
· <b>Upper:</b>	Not determined
· <b>Flash point:</b>	97 °C (2-hydroxyethyl methacrylate)
· <b>Auto-ignition temperature:</b>	Not determined
· <b>Decomposition temperature:</b>	Not determined.
· <b>pH</b>	Not determined
· <b>Viscosity:</b>	Not determined
· <b>Kinematic viscosity</b>	Not applicable.
· <b>Solubility</b>	
· <b>water:</b>	Not miscible or difficult to mix.
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined
· <b>Vapour pressure:</b>	Not determined
· <b>Density and/or relative density</b>	
· <b>Density:</b>	1.1 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Relative vapour density</b>	Not determined

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<b>· 9.2 Other information</b>	
<b>· Appearance:</b>	
<b>· Form:</b>	Liquid
<b>· Important information on protection of health and environment, and on safety.</b>	
<b>· Explosive properties:</b>	Product does not present an explosion hazard.
<b>· Change in condition</b>	
<b>· Softening point/range</b>	
<b>· Oxidising properties</b>	Not determined.
<b>· Evaporation rate</b>	Not determined.
<b>· Oxidising gases</b>	Void
<b>· Gases under pressure</b>	Void
<b>· Flammable liquids</b>	Void
<b>· Flammable solids</b>	Void
<b>· Self-reactive substances and mixtures</b>	Void
<b>· Pyrophoric liquids</b>	Void
<b>· Pyrophoric solids</b>	Void
<b>· Self-heating substances and mixtures</b>	Void
<b>· Substances and mixtures, which emit flammable gases in contact with water</b>	Void
<b>· Oxidising liquids</b>	Void
<b>· Oxidising solids</b>	Void
<b>· Organic peroxides</b>	Void
<b>· Corrosive to metals</b>	Void
<b>· Desensitised explosives</b>	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:**

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

Oral	LD50	4680 mg/kg (guinea pig)
		3275 mg/kg (mouse)
		5050 mg/kg (rat)

**94-36-0 benzoyl peroxide**

Oral	LD50	5700 mg/kg (mouse)
		7710 mg/kg (rat)
	LD50	250 mg/kg (mouse - intraperitoneal)

- **Skin corrosion/irritation**  
Causes skin irritation.

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**Safety data sheet**  
according to 1907/2006/EC, Article 31

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- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **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**  
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.

**SECTION 14: Transport information**

- |   |      |
|---|------|
| · <b>14.1 UN number or ID number</b><br>· <b>ADR, ADN, IMDG, IATA</b>                       | Void |
| · <b>14.2 UN proper shipping name</b><br>· <b>ADR, ADN, IMDG, IATA</b>                      | Void |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | Void |

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· <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.
- **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**

H241 Heating may cause a fire or explosion.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye 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

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