


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

- **1.1 Product identifier**
- **Trade name:** CLEARFIL AP-X, CLEARFIL AP-X PLT
- **Article number:** 017, 084
- **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**  
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)

Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT

(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	1-7%
EINECS: 203-652-6	⚠ Skin Sens. 1B, H317	
CAS: 94-36-0	benzoyl peroxide	0.1-1%
EINECS: 202-327-6	⚠ ⚠ Org. Perox. B, H241; ⚠ Eye Irrit. 2, H319; Skin Sens. 1, H317	

· **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.

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)

**Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT**

(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 cool location (2-25°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:**

**60676-86-0 Silica, fused**

WEL (Great Britain)	Long-term value: 0.08 mg/m <sup>3</sup> fused respirable dust
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**94-36-0 benzoyl peroxide**

WEL (Great Britain)	Long-term value: 5 mg/m <sup>3</sup>
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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)

**Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT**

(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 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>	Colored
· <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.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density at 20 °C:</b>	2.3 g/cm <sup>3</sup>
· <b>Relative vapour density</b>	Not applicable.
· <b>Particle characteristics</b>	See Section 3.

· **9.2 Other information**

· **Information with regard to physical hazard classes**

· <b>Explosives</b>	Product does not present an explosion hazard.
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <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

(Contd. on page 5)

Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT

(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.
- **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.
- **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.

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(Contd. on page 6)

## Safety data sheet according to UK REACH

Printing date 26.12.2024

Version number 9 (replaces version 8)

Revision date: 26.12.2024

**Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT**

(Contd. of page 5)

### 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>                                  | Void            |
| · <b>ADR, ADN, IMDG, IATA</b>   |                 |
| · <b>14.2 UN proper shipping name</b>                                 | Void            |
| · <b>ADR, ADN, IMDG, IATA</b>   |                 |
| · <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.

#### · **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.

(Contd. on page 7)

**Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT**

(Contd. of page 6)

· **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 Sheet 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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