

**\* 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.

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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:**

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:**

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

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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.

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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:**

Colored

**· 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:**2.3 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

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· <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** 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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<b>SECTION 13: Disposal considerations</b>	
<b>· 13.1 Waste treatment methods</b>	
<b>· Recommendation</b>	Must not be disposed together with household garbage. Do not allow product to reach sewage system.
<b>· Uncleaned packaging:</b>	
<b>· Recommendation:</b>	Dispose of packaging according to regulations on the disposal of packagings.

<b>SECTION 14: Transport information</b>	
<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

<b>SECTION 15: Regulatory information</b>	
<b>· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	
<b>· Regulated explosives precursors</b>	None of the ingredients is listed.
<b>· Regulated poisons</b>	None of the ingredients is listed.
<b>· Reportable explosives precursors</b>	None of the ingredients is listed.
<b>· Reportable poisons</b>	None of the ingredients is listed.
<b>· Directive 94/33/EC:</b>	Care should be taken when people under 18 handle this product.
<b>· Directive 94/85/EEC:</b>	No further relevant information available.
<b>· Named dangerous substances - ANNEX I</b>	None of the ingredient is listed.
<b>· Regulation (EU) No 649/2012</b>	None of the ingredients is listed.
<b>· Regulation (EC) No 273/2004 on drug precursors</b>	None of the ingredients is listed.

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- **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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