

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

Printing date 10.08.2016

Version number 6

Revision: 10.08.2016

**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 filling material**1.3 Details of the supplier of the safety data sheet****Manufacturer:**

Kuraray Europe GmbH  
Philipp-Reis-Str. 4,  
65795 Hattersheim am Main  
Germany  
Phone: +49 (0)69 305 35 840  
Fax: +49 (0)69 305 35 640  
E-mail: dental@kuraray.de

**Supplier:**

J & S Davis  
5 Whitworth Road, Stevenage,  
Hertfordshire, SG1 4QS  
Great Britain  
Tel: +44- (0) 1438 747344  
Fax: +44- (0)1438 758909  
E-mail: jsdsales@js-davis.co.uk

**Further information obtainable from:** Manufacturer or Supplier**1.4 Emergency telephone number:**

National Poisons information Service (London Centre)  
Guy's & St. Thomas' Hospital Trust  
Medical Toxicology Unit  
Avonley Road  
LONDON  
SE14 5ER  
Emergency telephone: (local) 0870 600 6266 or +44 20 7771 5394  
Administrative telephone: +44 20 7 771 53 10  
Facsimile number: +44 20 7 771 53 09

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

GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

**2.2 Label elements****Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

**Hazard pictograms** GHS07**Signal word** Warning**Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

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## Precautionary statements

- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P321 Specific treatment (see on this label).
- P332+P313 If skin irritation occurs: Get medical advice/attention.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P302+P352 IF ON SKIN: Wash with plenty of water.
- P362+P364 Take off contaminated clothing and wash it before reuse.

## Labelling of packages where the contents do not exceed 125 ml

## Hazard-determining components of labelling:

bisphenol A diglycidylmethacrylate  
triethyleneglycol dimethacrylate

## 2.3 Other hazards

## Results of PBT and vPvB assessment

- PBT: Not applicable.
- vPvB: Not applicable.

## SECTION 3: Composition/information on ingredients

### 3.1 Chemical characterisation: Substances None

### 3.2 Chemical characterisation: Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

### Dangerous components:

|                                     |                                                                                                 |      |
|-------------------------------------|-------------------------------------------------------------------------------------------------|------|
| CAS: 1565-94-2<br>EINECS: 216-367-7 | bisphenol A diglycidylmethacrylate<br>⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319                 | <12% |
| CAS: 109-16-0<br>EINECS: 203-652-6  | triethylene glycol dimethacrylate<br>⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | <5%  |

### Other ingredients:

Silanated barium glass filler  
Silanated silica filler  
Silanated colloidal silica  
dl-Camphorquinone  
Catalysts  
Accelerators  
Pigments

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Immediately wash with water and soap and rinse thoroughly.
- After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- 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.

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**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:** No special measures required.

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections** No dangerous substances are released.

**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** No special measures required.
- **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.  
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.

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**SECTION 8: Exposure controls/personal protection**

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**



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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Safety glasses

## SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

|         |           |
|---------|-----------|
| Form:   | Pasty     |
| Colour: | Coloured  |
| Odour:  | Odourless |

· **pH-value:** Not determined

· **Change in condition**

|                              |                |
|------------------------------|----------------|
| Melting point/Melting range: | Not determined |
| Boiling point/Boiling range: | Not determined |

· **Flash point:** Not determined

· **Ignition temperature:** Not determined

· **Decomposition temperature:** Not determined

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

|        |                |
|--------|----------------|
| Lower: | Not determined |
| Upper: | Not determined |

· **Oxidising properties** Not determined

· **Vapour pressure:** Not applicable

|                  |                       |
|------------------|-----------------------|
| Density:         | 2.3 g/cm <sup>3</sup> |
| Relative density | Not determined        |
| Vapour density   | Not determined        |
| Evaporation rate | Not determined        |

· **Solubility in / Miscibility with water:** Insoluble.

· **Partition coefficient (n-octanol/water):** Not applicable

· **Viscosity:** Not determined

· **9.2 Other information** No further relevant information available.

## 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.

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- **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 toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

**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.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

**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.

**SECTION 14: Transport information**

- |                                       |      |
|---------------------------------------|------|
| · <b>14.1 UN-Number</b>               |      |
| · <b>ADR, ADN, IMDG, IATA</b>         | Void |
| · <b>14.2 UN proper shipping name</b> |      |
| · <b>ADR, ADN, IMDG, IATA</b>         | Void |

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- |                                                                                  |                 |
|----------------------------------------------------------------------------------|-----------------|
| · <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 Transport in bulk according to Annex II of Marpol and the IBC Code</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**  
No further relevant information available.
- **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**  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.
- **Abbreviations and acronyms:**  
Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- **\* Data compared to the previous version altered.**

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