



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

- **Product identifier**
- **Trade name:** CLEARFIL AP-X, CLEARFIL AP-X PLT
- **Article number:** US017-084
- **Application of the substance / the preparation** Dental filling material
- **Details of the supplier of the safety data sheet**
- **Manufacturer:**  
Kuraray Noritake Dental Inc.  
1621 Sakazu, Kurashiki, Okayama 710-0801,  
Japan
- **Contact information:**  
Kuraray America, Inc.  
33 Maiden Lane, 6th Floor, New York,  
NY 10038 U.S.A.  
Tel: 800-879-1676  
Fax: 888-700-5200  
Website: www.kuraraydental.com

## 2 Composition/information on ingredients

- **Chemical characterization:** Single Component
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

1565-94-2	bisphenol A diglycidylmethacrylate	 H315; H319	<12%
109-16-0	triethylene glycol dimethacrylate	 H315; H319; H335	<5%

- **Other ingredients:**  
Silanated barium glass filler  
Silanated silica filler  
Silanated colloidal silica  
dl-Camphorquinone  
Catalysts  
Accelerators  
Pigments  
Others

## 3 Hazards identification

- **Classification of the substance or mixture**



GHS07

H315 Causes skin irritation.

H319 Causes serious eye irritation.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.

- **Information concerning particular hazards for human and environment:**

The product does not have to be labelled due to the calculation procedure of international guidelines.

- **Classification system:**

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

- **Label elements**

- **GHS label elements**

The product is classified and labelled according to the Globally Harmonized System (GHS).

- **Hazard pictograms** GHS07

- **Signal word** Warning

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· **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

· **Precautionary statements**

P280 Wear protective gloves/protective clothing/eye protection/face protection.

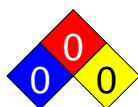
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P362 Take off contaminated clothing and wash before reuse.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

· **Classification system:**· **NFPA ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

HEALTH

0

Health = 0

FIRE

0

Fire = 0

REACTIVITY

0

Reactivity = 0

**4 First aid measures**

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **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:** If symptoms persist consult doctor.

**5 Firefighting measures**

- **Suitable extinguishing agents:** CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

**6 Accidental release measures**

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

**7 Handling and storage**

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **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:** None.

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· **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Components 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 that were valid during the creation were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.
- **Protection of hands:**  
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 protection:** Not required.

### 9 Physical and chemical properties

· <b>General Information</b>	
· <b>Appearance:</b>	
<b>Form:</b>	Pasty
<b>Color:</b>	Colored
· <b>Odor:</b>	Odorless
· <b>pH-value:</b>	Not applicable
· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Ignition temperature:</b>	Not applicable
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not applicable
<b>Upper:</b>	Not applicable
· <b>Vapor pressure:</b>	Not applicable
· <b>Density:</b>	2.3 g/cm <sup>3</sup> (19.194 lbs/gal)
· <b>Vapour density</b>	Not applicable

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- |   |  |
|---|--|
| · <b>Solubility in / Miscibility with Water:</b>    | Insoluble.                                 |
| · <b>Segregation coefficient (n-octanol/water):</b> | Not applicable                             |
| · <b>Other information</b>                          | No further relevant information available. |

### 10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used and stored according to specifications.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

### 11 Toxicological information

- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The product is not subject to classification according to internally approved calculation methods for preparations:  
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

### 12 Ecological information

- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability:** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential:** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water

### 13 Disposal considerations

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

### 14 Transport information

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

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· <b>Transport hazard class(es)</b>	
· <b>DOT, ADR, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>Packing group</b>	
· <b>DOT, ADR, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	-

### 15 Regulatory information

· <b>Sara</b>
· <b>Section 355 (extremely hazardous substances):</b>
None of the ingredient is listed.
· <b>Section 313 (Specific toxic chemical listings):</b>
None of the ingredients is listed.
· <b>TSCA (Toxic Substances Control Act):</b>
All ingredients are listed.
· <b>Proposition 65</b>
· <b>Chemicals known to cause cancer:</b>
None of the ingredients is listed.
· <b>Chemicals known to cause reproductive toxicity for females:</b>
None of the ingredients is listed.
· <b>Chemicals known to cause reproductive toxicity for males:</b>
None of the ingredients is listed.
· <b>Chemicals known to cause developmental toxicity:</b>
None of the ingredients is listed.
· <b>Carcinogeny categories</b>
· <b>EPA (Environmental Protection Agency)</b>
None of the ingredients is listed.
· <b>IARC (International Agency for Research on Cancer)</b>
None of the ingredients is listed.
· <b>TLV (Threshold Limit Value established by ACGIH)</b>
None of the ingredients is listed.
· <b>NIOSH-Ca (National Institute for Occupational Safety and Health)</b>
None of the ingredients is listed.
· <b>OSHA-Ca (Occupational Safety &amp; Health Administration)</b>
None of the ingredients is listed.

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**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.

· **Version:** 3

· **Relevant phrases**

Not applicable

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

USA