

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**



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

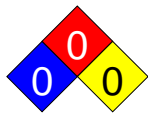
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.

· 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
Fire = 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:** CO₂, 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.

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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

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

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- | | |
|---|--|
| · Solubility in / Miscibility with Water: | Insoluble. |
| · Segregation coefficient (n-octanol/water): | Not applicable |
| · Other information | 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

- | | |
|------------------------------------|------|
| · UN-Number | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, ADR, ADN, IMDG, IATA | Void |

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

15 Regulatory information

· Sara

· **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogeny categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

USA

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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