

## 1 Identification of substance

- **Product details**
- **Trade name:** CLEARFIL AP-X, CLEARFIL AP-X PLT
- **Article number:** US017-084
- **Application of the substance / the preparation** Dental filling material
- **Manufacturer:**  
Kuraray Medical Inc.  
1621 Sakazu, Kurashiki, Okayama 710-0801,  
Japan
- **Supplier:**  
Kuraray America, Inc.  
600 Lexington Avenue, 26th Floor, New York,  
NY 10022 U.S.A.  
Tel: 800-879-1676  
Fax: 888-700-5200  
Website: www.kuraraydental.com
- **Information department:** Supplier

## 2 Composition/Data on components

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

- **Dangerous components:**

1565-94-2	bisphenol A diglycidylmethacrylate	Warning:  3.2/2, 3.3/2A	<12%
109-16-0	triethylene glycol dimethacrylate	Warning:  3.2/2, 3.3/2A, 3.8/3	<5%

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

## 3 Hazards identification

- **Hazard description:** Not applicable.
- **Information pertaining to particular dangers for man 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.
- **NFPA ratings (scale 0 - 4)**  
Health = 0  
Fire = 0  
Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**  
Health = 0  
Fire = 0  
Reactivity = 0
- **GHS label elements**

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#### 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 Fire fighting measures

- **Suitable extinguishing agents:** CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:** No special measures required.

#### 6 Accidental release measures

- **Person-related safety precautions:** Not required.
- **Measures for environmental protection:** No special measures required.
- **Measures for cleaning/collecting:** Pick up mechanically.
- **Additional information:** No dangerous substances are released.

#### 7 Handling and storage

- **Handling:**
- **Information 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.

#### 8 Exposure controls and 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.

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- **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

<b>Form:</b>	Pasty
<b>Color:</b>	Colored
<b>Odor:</b>	Odorless

### · Change in condition

<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

· **Ignition temperature:** Not applicable

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

### · Explosion limits:

<b>Lower:</b>	Not applicable
<b>Upper:</b>	Not applicable

· **Vapor pressure:** Not applicable

· <b>Density:</b>	2.3 g/cm <sup>3</sup>
· <b>Vapour density</b>	Not applicable

### · Solubility in / Miscibility with

<b>Water:</b>	Insoluble.
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· **pH-value:** Not applicable

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

## 10 Stability and reactivity

### · Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to specifications.

· **Dangerous reactions** No dangerous reactions known.

· **Dangerous products of decomposition:** 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:

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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. (Contd. of page 3)

## 12 Ecological information

- **General notes:** Generally not hazardous for water

## 13 Disposal considerations

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

## 14 Transport information

- **DOT regulations:**
- **Hazard class:** -
- **Land transport ADR/RID (cross-border):**
- **ADR/RID class:** -
- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -
- **UN "Model Regulation":** -

## 15 Regulations

- **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.

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· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

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.

· **Product related hazard informations:**

Observe the general safety regulations when handling chemicals.

The product is not subject to identification regulations according to directives on hazardous materials.

**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: 2**

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises Dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement internationale concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

ACGIH: American Conference of Governmental Industrial Hygienists

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)