

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

075216130

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

075215777 075183926 075183934 075183942 075183959 075183967 075183975 075183983 075183991 075184007  
075215769 075215785 75216015 75216023 75216049

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

075216015 075216023 075216049

**1 Identification**

- **Product identifier**
- **Trade name:** CLEARFIL AP-X, CLEARFIL AP-X PLT
- **Article number:** US017-084
- **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
- **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
- **Emergency telephone number:**  
For chemical emergency spill, leak, fire, exposure or accident  
Call CHEMTREC day and night  
Within USA and Canada: 1-800-424-9300 CCN706984 or  
+1 703-527-3887 (collect calls accepted)

**2 Hazard(s) identification**

- **Classification of the substance or mixture**



- Skin Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 2A H319 Causes serious eye irritation.

- **Label elements**
- **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard statements**  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.
- **Precautionary statements**  
P280 Wear protective gloves / eye protection / face protection.  
P302+P352 IF ON SKIN: Wash with plenty of water.  
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.  
P362+P364 Take off contaminated clothing and wash it before reuse.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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US

**Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT**

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· **vPvB:** Not applicable.

**3 Composition/information on ingredients**

- **Chemical characterization: Substances** None
- **Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· <b>Dangerous components:</b>		
1565-94-2	bisphenol A diglycidylmethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319	<12%
109-16-0	triethylene glycol dimethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	<5%

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

**4 First-aid measures**

- **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.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
 No further relevant information available.

**5 Fire-fighting measures**

- **Extinguishing media**
- **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.
- **Advice for firefighters**
- **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.

**Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT**

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**7 Handling and storage**

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **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 receptacle tightly sealed.  
Store in cool, dry conditions in well sealed receptacles.  
Protect from heat and direct sunlight.
- **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.
- **Control parameters**
- **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.
- **Exposure controls**
- **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:**



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.

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.

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US

**Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT**

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**· Eye protection:**



Tightly sealed goggles

**9 Physical and chemical properties**

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

**· General Information**

**· Appearance:**

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

**· pH-value:** Not determined

**· Change in condition**

<b>Melting point/Melting range:</b>	Not determined
<b>Boiling point/Boiling range:</b>	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:**

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

**· Oxidizing properties** Not determined

**· Vapor pressure:** Not applicable

<b>· Density:</b>	2.3 g/cm <sup>3</sup>
<b>· Relative density</b>	Not determined
<b>· Vapor density</b>	Not determined
<b>· Evaporation rate</b>	Not determined

**· Solubility in / Miscibility with**

**Water:** Insoluble.

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

**· Viscosity:** Not determined

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

**10 Stability and reactivity**

**· Reactivity** No further relevant information available.

**· Chemical stability**

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

No decomposition if used and stored according to specifications.

**· Possibility of hazardous reactions** No dangerous reactions known.

**· Conditions to avoid** No further relevant information available.

**· Incompatible materials:** No further relevant information available.

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**Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT**

**Hazardous decomposition products:** Carbon monoxide and carbon dioxide (Contd. of page 4)

**11 Toxicological information**

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** 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.

· **Carcinogenic categories**

· <b>IARC (International Agency for Research on Cancer)</b>
None of the ingredients is listed.
· <b>NTP (National Toxicology Program)</b>
None of the ingredients is listed.

**12 Ecological information**

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

**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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**Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT**

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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>	Void

**15 Regulatory information**

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
· **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.

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**  
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.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**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.

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Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT

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· **Relevant phrases**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

· **NFPA ratings (scale 0 - 4)**

Health = 1

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 1

Fire = 0

Reactivity = 0

· **Abbreviations and acronyms:**

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· **\* Data compared to the previous version altered.**



**1 Identification**

- **Product identifier**
- **Trade name:** CLEARFIL AP-X, CLEARFIL AP-X PLT
- **Article number:** CA017-084
- **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
- **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
- **Emergency telephone number:**  
For chemical emergency spill, leak, fire, exposure or accident  
Call CHEMTREC day and night  
Within USA and Canada: 1-800-424-9300 CCN706984 or  
+1 703-527-3887 (collect calls accepted)

**2 Hazard(s) identification**

- **Classification of the substance or mixture**



Skin Irritation - Category 2 H315 Causes skin irritation.  
Eye Irritation - Category 2A H319 Causes serious eye irritation.

- **Label elements**
- **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard statements**  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.
- **Precautionary statements**

P264	Wash thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	If on skin: Wash with plenty of water.
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.
P362+P364	Take off contaminated clothing and wash it before reuse.
- **Hazard-determining components of labeling:**  
bisphenol A diglycidylmethacrylate

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CA

**Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT**

triethyleneglycol dimethacrylate

(Contd. of page 1)

**3 Composition/information on ingredients**

- **Chemical characterization: Substances** None
- **Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

1565-94-2	bisphenol A diglycidylmethacrylate ⚠ Skin Irritation - Category 2, H315; Eye Irritation - Category 2A, H319	10-25% w/w
109-16-0	triethylene glycol dimethacrylate ⚠ Skin Irritation - Category 2, H315; Eye Irritation - Category 2A, H319; Specific Target Organ Toxicity - Single Exposure - Category 3, H335	2.5-10% w/w

· **Other ingredients:**

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

**4 First-aid measures**

- **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.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

**5 Fire-fighting measures**

- **Extinguishing media**
- **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.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

**6 Accidental release measures**

- **Personal precautions, protective equipment and emergency procedures** See Section 8.
- **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.

**Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT**

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## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **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 receptacle tightly sealed.  
Store in cool, dry conditions in well sealed receptacles.  
Protect from heat and direct sunlight.
- **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.
- **Control parameters**
- **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.
- **Exposure controls**
- **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:**



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.

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.

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CA

Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT

(Contd. of page 3)

## · Eye protection:



Tightly sealed goggles

## 9 Physical and chemical properties

## · Information on basic physical and chemical properties

## · General Information

## · Appearance:

· Form:	Pasty
· Color:	Colored
· Odor:	Odorless

· 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

· Oxidizing properties: Not determined

· Vapor pressure: Not applicable

· Density:	2.3 g/cm <sup>3</sup>
· Relative density	Not determined
· Vapor density	Not determined
· Evaporation rate	Not determined

## · Solubility in / Miscibility with

· Water: Insoluble.

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

· Viscosity: Not determined

· Other information: No further relevant information available.

## 10 Stability and reactivity

· Reactivity: No further relevant information available.

## · Chemical stability

## · Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to specifications.

· Possibility of hazardous reactions: No dangerous reactions known.

· Conditions to avoid: No further relevant information available.

· Incompatible materials: No further relevant information available.

(Contd. on page 5)

**Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT**

· **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

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**11 Toxicological information**

· **Information on toxicological effects**

· **Acute toxicity:**

· **Primary irritant effect:**

· **on the skin:** Irritant to skin and mucous membranes.

· **on the eye:** 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.

· **Carcinogenic categories**

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

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

**12 Ecological information**

· **Toxicity**

· **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.

· **Mobility in soil** No further relevant information available.

· **Additional ecological information:**

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

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

**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, TDG, ADN, IMDG, IATA** Void

· **UN proper shipping name**

· **DOT, ADN, IMDG, IATA** Void

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**Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT**

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· <b>TDG</b>	Void
· <b>Transport hazard class(es)</b>	
· <b>DOT, TDG, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>Packing group</b>	
· <b>DOT, TDG, 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>	Void

**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.

· **SARA 311/312:** See Section 2 for the information on physical and health hazards.

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

All ingredients are listed.

· **Canadian substance listings:**

· **Canadian Domestic Substances List (DSL)**

All ingredients are listed.

· **Canadian Ingredient Disclosure list (limit 0.1%)**

None of the ingredients is listed.

· **Canadian Ingredient Disclosure list (limit 1%)**

109-16-0 | triethylene glycol dimethacrylate

**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.

· **\* Data compared to the previous version altered.**