

1 Identification

- **Product identifier**
- **Trade name:** CLEARFIL AP-X, CLEARFIL AP-X PLT
- **Other means of identification**
- **Article number:** US017, US084
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Dental materials
- **Details of the supplier of the safety data sheet**
- **Contact information :**
Kuraray America, Inc.
32 Old Slip, 7th Floor, New York,
NY 10005 U.S.A.
Tel: 800-879-1676
Website: www.kuraraydental.com
- **Emergency telephone number:**
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**
Sensitization - skin 1 H317 May cause an allergic skin reaction.

- **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-determining components of labeling:**
Triethyleneglycol dimethacrylate
benzoyl peroxide
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P280 Wear protective gloves / eye protection / face protection.
P302+P352 If on skin: Wash with plenty of water.
P362+P364 Take off contaminated clothing and wash it before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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3 Composition/information on ingredients

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

· **Dangerous components:**

| | | |
|----------|---|--------|
| 109-16-0 | Triethyleneglycol dimethacrylate ⚠ Sensitization - skin 1B, H317 | 1-7% |
| 94-36-0 | benzoyl peroxide ⚠ Organic peroxides - Type B, H241; ⚠ Eye irritation 2A, H319; Sensitization - skin 1, H317 | 0.1-1% |

4 First-aid measures

- **Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult 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.
Use fire fighting measures that suit the environment.
- **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:**
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
Contain spill, then place in a suitable container. Minimize dust generation. Do not flush to sewer or allow to enter waterways.
Vacuum or sweep material and place in a disposal container. Provide ventilation.
Use appropriate Personal Protective Equipment (PPE).
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

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7 Handling and storage

- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Avoid contact with skin and eyes, Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors /spray.
- **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.
Protect from heat and direct sunlight.
Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

60676-86-0 Silica, fused

| | |
|-----|---------------------------|
| PEL | 20mppcf or 80mg/m3 /%SiO2 |
| TLV | TLV withdrawn |

94-36-0 benzoyl peroxide

| | |
|-----|--------------------------------------|
| PEL | Long-term value: 5 mg/m ³ |
| REL | Long-term value: 5 mg/m ³ |
| TLV | Long-term value: 5 mg/m ³ |
| | A4 |

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Appropriate engineering controls** No further data; see section 7.

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

· **Breathing equipment:** Suitable respiratory protective device recommended.

· **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.

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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:** Safety glasses

9 Physical and chemical properties

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

· **General Information**

- **Physical state** Solid
- **Color:** Colored
- **Odor:** Odorless
- **Odor threshold:** Not determined.
- **Melting point/Melting range:** Not determined.
- **Boiling point/Boiling range:** Not determined.
- **Flammability:** Not determined.
- **Explosion limits:**
- **Lower:** Not applicable.
- **Upper:** Not applicable.
- **Flash point:** Not applicable
- **Auto ignition temperature:** Not applicable.
- **Decomposition temperature:** Not applicable.
- **pH-value:** Not determined.
- **Kinematic viscosity** Not applicable.
- **Solubility in / Miscibility with**
- **Water:** Insoluble.
- **Partition coefficient (n-octanol/water):** Not applicable.
- **Vapor pressure:** Not applicable.
- **Density at 20 °C:** 2.3 g/cm³
- **Relative density** Not determined.
- **Relative vapor density** Not applicable.
- **Particle characteristics** Not determined.

· **Other information**

· **Important information on protection of health and environment, and on safety.**

- **Danger of explosion:** Product does not present an explosion hazard.
- **Evaporation rate** Not applicable.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** No hazardous reaction when handled and stored according to provisions.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:** Based on available data, the classification criteria are not met.
- **Sensitization:** Sensitization possible through skin contact.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

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· **Subacute to chronic toxicity:**

· **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.

· **Bioaccumulative potential** No further relevant information available.

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

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects**

· **Additional ecological information:**

· **General notes:** Not hazardous for water.

13 Disposal considerations

· **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

· **Recommendation:** Dispose of packaging according to regulations on the disposal of packagings.

14 Transport information

· **UN-Number**

· **DOT, IMDG, IATA** Void

· **UN proper shipping name**

· **DOT, IMDG, IATA** Void

· **Transport hazard class(es)**

· **DOT, IMDG, IATA**

· **Class** Void

· **Packing group**

· **DOT, IMDG, IATA** Void

· **Environmental hazards:** Not applicable.

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

· **Special precautions for user** Not applicable.

· **UN "Model Regulation":** Void

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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):**
94-36-0 benzoyl peroxide

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

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

| | | |
|------------|----------------------------------|--------|
| 109-16-0 | Triethyleneglycol dimethacrylate | ACTIVE |
| 60676-86-0 | Silica, fused | ACTIVE |
| 94-36-0 | benzoyl peroxide | ACTIVE |

· **Hazardous Air Pollutants**
None of the ingredients is 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)**
None of the ingredients is listed.

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**
H241 Heating may cause a fire or explosion.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



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Safety Data Sheet
acc. to OSHA HCS

Date of issue: 12/26/2024

Version 6

Reviewed on 12/26/2024

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

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- **Date of previous version** 12/27/2023
- **Version number of previous version:** 5
- **Date of preparation** 12/26/2024
- **Abbreviations and acronyms:**
 - DOT: US Department of Transportation
 - ELINCS: European List of Notified Chemical Substances
 - TLV: Threshold Limit Value
 - PEL: Permissible Exposure Limit
 - REL: Recommended Exposure Limit
 - Organic peroxides - Type B: Organic peroxides – Type B
 - Eye irritation 2A: Serious eye damage/eye irritation – Category 2A
 - Sensitization - skin 1: Skin sensitisation – Category 1
 - Sensitization - skin 1B: Skin sensitisation – Category 1B
- *** Data compared to the previous version altered.**

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