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

2 Hazard(s) identification

- Classification of the substance or mixture
  GHS07
  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.
3 Composition/information on ingredients

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

<table>
<thead>
<tr>
<th>Dangerous components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1565-94-2 bisphenol A diglycidylmethacrylate</td>
<td>&lt;12%</td>
</tr>
<tr>
<td>Skin Irrit. 2, H315; Eye Irrit. 2Ã‚Â, H319</td>
<td></td>
</tr>
<tr>
<td>109-16-0 triethylene glycol dimethacrylate</td>
<td>&lt;5%</td>
</tr>
<tr>
<td>Skin Irrit. 2, H315; Eye Irrit. 2Ã‚Â, H319; STOT SE 3, H335</td>
<td></td>
</tr>
</tbody>
</table>

- 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.
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:
  - 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.
  - 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 cannot 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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9 Physical and chemical properties

- **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/cm³
- **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.
Trade name: CLEARFIL AP-X, CLEARFIL AP-X PLT

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, 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": 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.

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

- 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.