1 Identification of the substance/mixture and of the company/undertaking

- Product identifier
- Trade name: Amelogen™ Plus
- Article number:
  71138, 71140, 71141, 71142, 71143, 71144, 71147, 71148, 71150, 71151, 71152, 71153, 71154, 71155, 71157, 71158, 72638
- Index number: SDS 1-001.14
- Relevant identified uses of the substance or mixture and uses advised against Professional Dental Composite
  - Application of the substance / the mixture Professional Dental Composite
- Details of the supplier of the safety data sheet
  - Manufacturer/Supplier:
    Ultradent Products Inc.
    505 W. Ultradent Drive (10200 S)
    South Jordan, UT 84095-3942
    USA
    onlineordersupport@utradent.com

  EC Responsible Person
  Ultradent Products GmbH
  Am Westhover Berg 30
  51149 Cologne Germany
  Email: infoDe@ultradent.com
  Emergency Phone: +49(0)2203-35-92-0

- Further information obtainable from: Customer Service
- Emergency telephone number:
  CHEMTREC (NORTH AMERICA) : (800) 424-9300
  (INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008

⚠ GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

- Label elements
- Labelling according to Regulation (EC) No 1272/2008
  The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
- Hazard pictograms GHS07
- Signal word Warning
- Hazard-determining components of labelling:
  Triethylene Glycol Dimethacrylate
- Hazard statements
  H317 May cause an allergic skin reaction.

(Contd. on page 2)
Trade name: Amelogen™ Plus

3 Composition/information on ingredients

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

- Dangerous components:
  - CAS: 109-16-0  Triethylene Glycol Dimethacrylate
  - EINECS: 203-652-6
  - Skin Sens. 1, H317 >2.5-<10%

- Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- Description of first aid measures
- General information: Immediately remove any clothing soiled by the product.

- After inhalation:
  - This product is a thick paste, therefore inhalation is extremely unlikely.
  - Supply fresh air and to be sure call for a doctor.

- 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.

- 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 Firefighting measures

- Extinguishing media
- Suitable extinguishing agents:
  - Water spray
  - Foam
  - Carbon dioxide
  - Use fire extinguishing methods suitable to surrounding conditions.

- Special hazards arising from the substance or mixture: No further relevant information available.
Trade name: Amelogen™ Plus

· Advice for firefighters:
· Protective equipment: Wear fully protective suit.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures Not required.
· Environmental precautions: Do not allow to enter sewers/surface or ground water.
· Methods and material for containment and cleaning up:
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  Dispose contaminated material as waste according to item 13.
  Ensure adequate ventilation.
· 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.

7 Handling and storage

· Handling:
· Precautions for safe handling:
  Ensure good ventilation/exhaustion at the workplace.
  Prevent formation of aerosols.
· Information about fire - and explosion protection: 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.
  Information about storage in one common storage facility: Not required.
· Further information about storage conditions:
  See product labelling.
  Store in a cool place.
  Protect from heat
· Specific end use(s) Professional Dental Composite

8 Exposure controls/personal protection

· Additional information about design of technical facilities: No further data; see item 7.
· Control parameters
· Ingredients 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 valid during the making were used as basis.
· Exposure controls
· Personal protective equipment:
· General protective and hygienic measures:
  Avoid contact with the eyes and skin.
  Immediately remove all soiled and contaminated clothing.
  Wash hands before breaks and at the end of work.
· Respiratory protection:
  In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
Trade name: Amelogen™ Plus

- 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 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 breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- Eye protection: Goggles recommended during refilling

- Body protection: Protective work clothing

9 Physical and chemical properties

- Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance:</strong></td>
</tr>
<tr>
<td>Form: Paste</td>
</tr>
<tr>
<td>Colour: According to product specification</td>
</tr>
<tr>
<td>Odour: Acrylic</td>
</tr>
<tr>
<td>Odour threshold: Not determined.</td>
</tr>
<tr>
<td>pH-value: Not applicable (non-aqueous)</td>
</tr>
</tbody>
</table>

- Change in condition

| Melting point/freezing point: Undetermined. |
| Initial boiling point and boiling range: Undetermined. |

- Flash point: Not applicable.

- Flammability (solid, gas): Not applicable.

- Decomposition temperature: Not determined.

- Auto-ignition temperature: Product is not selfigniting.

- Explosive properties: Product does not present an explosion hazard.

- Explosion limits:

  | Lower: Not determined. |
  | Upper: Not determined. |

- Vapour pressure: Not determined.

- Density at 20 °C: 2-2.1 g/cm³

- Relative density: Not determined.

- Vapour density: Not determined.

- Evaporation rate: Not determined.
Trade name: Amelogen™ Plus

Solubility in / Miscibility with water: Not miscible or difficult to mix.

Partition coefficient: n-octanol/water: Not determined.

Viscosity:
Dynamic: Not determined.
Kinematic: Not determined.

Solvent content:
VOC (EC) 0.00 %

Other information No further relevant information available.

10 Stability and reactivity

Reactivity Polymerization under the influence of light.
Chemical stability
Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
Possibility of hazardous reactions: No dangerous reactions known.
Conditions to avoid:
Light
Flames
Heat
Incompatible materials: No further relevant information available.
Hazardous decomposition products: Carbon dioxide

11 Toxicological information

Information on toxicological effects
Acute toxicity Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification:

<table>
<thead>
<tr>
<th>109-16-0 Triethylene Glycol Dimethacrylate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD50 &gt;5,000 mg/kg (rat)</td>
</tr>
<tr>
<td>LC50 Fish 16.4 mg/l (Fish) (Toxicity to fish)</td>
</tr>
<tr>
<td>Dermal LD50 &gt;2,000 mg/kg (mouse)</td>
</tr>
</tbody>
</table>

Primary irritant effect:
Skin corrosion/irritation Based on available data, the classification criteria are not met.
Serious eye damage/irritation Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation
May cause an allergic skin reaction.
CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
Germ cell mutagenicity Based on available data, the classification criteria are not met.
Carcinogenicity Based on available data, the classification criteria are not met.
Reproductive toxicity Based on available data, the classification criteria are not met.
STOT-single exposure Based on available data, the classification criteria are not met.
STOT-repeated exposure Based on available data, the classification criteria are not met.
Aspiration hazard Based on available data, the classification criteria are not met.
# 12 Ecological information

## Toxicity

### Aquatic toxicity:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Biodegradability</th>
<th>Aquatic toxicity</th>
<th>EC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>109-16-0 Triethylene Glycol Dimethacrylate</td>
<td>28 days (Aerobic) (Biodegradability testing)</td>
<td>32 mg/l (daphnia) (No Observed Effect Concentration)</td>
<td>&gt;100 mg/l (Algae) (Toxicity to algae)</td>
</tr>
</tbody>
</table>

### Persistence and degradability

No further relevant information available.

### Behaviour in environmental systems:

- Bioaccumulative potential: No further relevant information available.
- Mobility in soil: No further relevant information available.

### Additional ecological information:

- General notes:
  - Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
  - Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

### Results of PBT and vPvB assessment

- PBT: Not applicable.
- vPvB: Not applicable.

### Other adverse effects

No further relevant information available.

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# 13 Disposal considerations

## Waste treatment methods

### Recommendation

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

### Uncleaned packaging:

### Recommendation: Disposal must be made according to official regulations.

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# 14 Transport information

## UN-Number

- ADR, IMDG, IATA: not regulated

## UN proper shipping name

- ADR, IMDG, IATA: not regulated

## Transport hazard class(es)

- ADR, ADN, IMDG, IATA: not regulated

## Packing group

- ADR, IMDG, IATA: not regulated

## Environmental hazards:

- Not applicable.

## Special precautions for user

- Not applicable.

## Transport in bulk according to Annex II of Marpol and the IBC Code

- Not applicable.


15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture
  · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
· Chemical safety assessment:
  Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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
  H317 May cause an allergic skin reaction.
· Department issuing SDS: Regulatory Affairs
· Contact: Customer Service
· 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)
  IMDG: International Maritime Code for Dangerous Goods
  IATA: International Air Transport Association
  GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  EINECS: European Inventory of Existing Commercial Chemical Substances
  ELINCS: European List of Notified Chemical Substances
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  VOC: Volatile Organic Compounds (USA, EU)
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative
  Skin Sens. 1: Skin sensitisation – Category 1