SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

Amelogen® Plus

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier
Product code : 72638, 71138, 71140, 71141, 71142, 71143, 71144, 71147, 71148, 71150, 71151, 71152, 71153, 71154, 71155, 71157
Product name : Amelogen® Plus
Product description : Composite restorative material

1.2. Relevant identified uses of the substance or mixture and uses advised against
Relevant identified uses : Professional Dental Composite

1.3. Details of the supplier of the safety data sheet
Manufacturer : Ultradent Products, Inc.
505 W. Ultradent Drive (10200 South)
South Jordan, UT 84095
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

1.4. Emergency telephone number
CHEMTREC (NORTH AMERICA) : (800) 424 - 9300
(INTERNATIONAL) : +1(703) 527 - 3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
Classification according to Regulation(EC) No 1272/2008 [CLP]
: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Health : Skin Sensitization, Category 1
: Skin Irritation, Category 2
: Eye Irritation, Category 2B

2.2. Label elements
Classification according to Regulation(EC) No 1272/2008 [CLP]

Hazard pictogram(s) : !
Exclamation mark

Signal Word : WARNING

Hazard statement(s) : H319: Causes serious eye irritation.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.

Precautionary statement(s)
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Prevention
- P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response
- P305: IF IN EYES:
  - P351: Rinse cautiously with water for several minutes.
  - P337+P313: If eye irritation persists: Get medical advice/attention.
- P302+P352: IF ON SKIN: Wash with plenty of soap & water.
  - P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

Storage
- P103: Read label before use.

Disposal

2.3. Other hazards

Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

SECTION 3: Composition / information on ingredients

3.1. Substances
Not Applicable

3.2. Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bis-GMA</td>
<td>1565-94-2</td>
<td>216-367-7</td>
<td>&lt;60</td>
<td>H315; H317; H319</td>
</tr>
<tr>
<td>TEGDMA</td>
<td>109-16-0</td>
<td>203-652-6</td>
<td>&lt;40</td>
<td>Skin Sens., Cat. 1B; H317</td>
</tr>
<tr>
<td>BHT</td>
<td>128-37-0</td>
<td>204-881-4</td>
<td>&lt;1</td>
<td>Aquatic Chronic, Cat. 1; H410</td>
</tr>
<tr>
<td>Barium aluminosilicate glass powder</td>
<td>65997-17-3</td>
<td>NAP</td>
<td>&lt;35</td>
<td>Skin Irr., Cat. 2; Eye Irr., Cat. 2B; STOT SE, Cat. 3; H315; H319; H335</td>
</tr>
</tbody>
</table>

For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes
- Flush eye with water for 15 minutes. Get medical attention.

Following skin
- Remove contaminated clothing. Wash with soap and water. Get medical attention if irritation develops or persists.

Following ingestion
- If swallowed in small quantity the product is harmless, otherwise consult a doctor.

Following inhalation
- No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

4.2. Most important symptoms and effects, both acute and delayed

- **Eyes**: Causes eye irritation.
- **Skin**: May cause skin irritation and sensitization.
- **Ingestion**: None expected for this product.
Amelogen® Plus

Inhalation : None expected for this product.

4.3. Indication of any immediate medical attention and special treatment needed
Notes to physician : NAP

SECTION 5: Fire fighting measures

5.1. Extinguishing media
Extinguishing media : Foam, Carbon Dioxide, or Water Spray

5.2. Special hazards arising from the substance or mixture
Hazardous combustion products : Not Established

5.3. Advice for firefighters
Fire fighting procedures : As in any fire, wear self-contained breathing apparatus pressure-demand, (MSHA/NIOSH approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
General procedures : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions
Water spill : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up
Small Spill : Clean up spills immediately, observing precautions in Protective Equipment section.
Large Spill : After removal, flush contaminated area thoroughly with water.

6.4. Reference to other sections
Reference to other sections : NAP
Additional information : Refer particularly to local circumstances and regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
General procedures : Avoid contact with eyes, skin and clothing.
Handling : Keep away from heat and flame.
Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities
Shelf life : See product labeling

7.3. Specific end use(s)
Specific end use(s) : Professional Dental Composite

SECTION 8: Exposure controls / personal protection

8.1. Control parameters
Control parameters : Butylated Hydroxy Toluene CAS: 128-37-0
SAFETY DATA SHEET  
according to Regulation (EC) No. 453/2010 
Dental Use

Amelogen® Plus

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLV Inhalable fraction &amp; vapour</td>
<td>2mg/m³</td>
</tr>
<tr>
<td>MAK Inhalable fraction</td>
<td>20mg/m³</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>none</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>TWA 10mg/m³</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>10mg/m³</td>
</tr>
</tbody>
</table>

Butylated Hydroxy Toluene CAS: 128-37-0 International Control Parameters

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alberta</td>
<td>10mg/m³ TWA</td>
</tr>
<tr>
<td>British Columbia</td>
<td>2mg/m³ TWA aerosol, inhalable, and vapour</td>
</tr>
<tr>
<td>Ontario</td>
<td>2mg/m³ TWA inhalable fraction and vapour</td>
</tr>
<tr>
<td>Quebec</td>
<td>10mg/m³ STEV</td>
</tr>
</tbody>
</table>

Barium aluminosilicate glass CAS 65997-17-3
Maritime PEL: 15 mg/m³
NIOSH REL 3 fibers/cm³ TWA (fibers with diameter ≤ 3.5 micrometers & length ≥ 10 micrometers) ; 5 mg/m³ TWA (total fibrous glass)

### 8.2. Exposure controls

- **Eye/face protection**: Wear eye protection.
- **Skin protection**: Wear suitable protective clothing and gloves.
- **Respiratory protection**: Good general ventilation should be sufficient to control airborne levels.

### 9.1. Information on basic physical and chemical properties

- **Physical state**: Viscous paste
- **Colour**: Shade dependent.
- **Odour**: Acrylic
- **pH**: NAP (non-aqueous)
- **Specific gravity**: 2.0 to 2.1

### 9.2. Other information

- **Additional information**: No further relevant information available

### 10.1. Reactivity
Amelogen® Plus

Reactivity: Light exposure initiates polymerization

10.2. Chemical stability
Chemical stability: Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions
Hazardous polymerization: None

10.4. Conditions to avoid
Conditions to avoid: Light exposure

10.5. Incompatible materials
Incompatible materials: Not determined

10.6. Hazardous decomposition products
Hazardous decomposition products: Carbon dioxide

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Acute
Dermal LD₅₀: > 2100 mg/kg (mouse/rat/hamster)
Notes: ~90% of the mixture consists of components of unknown toxicity (dermal)

Oral LD₅₀: > 5100 mg/kg Rat OECD Test Guideline
Notes: ~81% of the mixture consists of components of unknown toxicity (oral).

Inhalation LC₅₀: Not able to calculate ATE mix (inhalation) due to lack of data on the components.

Germ cell mutagenicity: The components in this product are not reported to produce mutagenic effects in humans.

Carcinogenicity: None of the components are listed by IARC, NTP, or CA Prop 65 as carcinogens when used in the form in this mixture.

Reproductive toxicity: The components in this product are not reported to cause reproductive effects in humans.

Other information: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity
Aquatic toxicity (acute): Do not allow to enter sewers or drains that may lead to waterways.

12.2. Persistence and degradability
Persistence and degradability: Not classified

12.3. Bioaccumulative potential
Bioaccumulative potential: Not classified

12.4. Mobility in soil
Mobility in soil: Not available
### 12.5. Results of PBT and vPvB assessment

**Results of PBT and vPvB assessment**: Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

### 12.6. Other adverse effects

**Environmental data**: This product may be toxic to fish or other aquatic wildlife.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods


### SECTION 14: Transport information

#### 14.1. UN number

**UN number**: NAP

#### 14.2. UN proper shipping name

**UN proper shipping name**: Not Dangerous Goods

#### 14.3. Transport hazard class(es)

**Hazard classification**: NAP

#### 14.4. Packing group

**Packing group**: NAP

#### 14.5. Environmental hazards

**Marine pollutant #1**: NAP

#### 14.6. Special precautions for user

**ADR - road**: NAP

**RID - rail**: NAP

**IMDG - sea**: NAP

**IATA - air**: NAP

### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

**Transport in bulk**: NAP

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

**General comments**: Please refer to Medical Devices Directive 93/42/EEC.

#### 15.2. Chemical safety assessment

**Chemical safety assessment**: See Section 11

**Additional information**: This product is not considered dangerous for transportation.

### SECTION 16: Other information

**Relevant H-statements (number and text)**: Aquatic Chronic, Cat. 1: Chronic Hazards to the Aquatic Environment, Category
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full-text) 1

Eye Irr., Cat. 2B: Eye Irritation, Category 2B
STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract
Category 3
Skin Irr., Cat. 2: Skin Irritation, Category 2
Skin Sens., Cat. 1B: Skin Sensitization, Category 1B
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H410: Very toxic to aquatic life with long lasting effects.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 09/16/2016 SDS. Revised: Section 1: MSDS No,
PRODUCT CODE/ PART #. Section 4: NOTES TO PHYSICIAN. Section 6:
Section 9: COMMENTS, PERCENT VOLATILE. Section 11:
CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE
TOXICITY. Section 15: COMMENTS. Section 16: GENERAL STATEMENTS.

General statements : NAP = Not Applicable
NE = Not Established
TLV = Threshold Limit Value
PEL = Permittable exposure limits
MAK = Maximum Workplace Concentration
STEL = Short-term exposure limit
STEV = Short-term exposure value
TWA = Time Weighted Average
PPE = Personal Protective Equipment

Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and
recommendations are taken from sources (raw material SDS(s) and
manufacturer's knowledge) believed to be accurate; however, the manufacturer,
makes no warranty with respect to the accuracy of the information or the
suitability of the recommendation and assumes no liability to any user thereof.
Each user should review these recommendations in the specific context of the
intended use and determine whether they are appropriate.