

# SAFETY DATA SHEET

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

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 01/11/2006  
SDS No : 1-001.12  
Date Revised : 09/16/2016  
Revision No : 11

## Amelogen® Plus

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

#### 1.1. Product identifier

**Product code** : GZ/72638, HL/71138, HR/71140, HS/71141, HU/71142, MQ/71143, MR/71144, MT/71147, MW/71148, MX/71150, MY/71151, UE/71152, UI/71153

**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. 10200 S.  
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 Directive 1999/45/EC

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

**Danger symbols** : Xi

**R phrases** : R43,R36/38

##### Classification according to Regulation(EC) No 1272/2008 [CLP]

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

**Environmental** : Chronic Hazards to the Aquatic Environment, Category 1

#### 2.2. Label elements

##### Classification according to Directive 1999/45/EC

**Hazard pictogram(s)** : Xi



Irritant

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**R& statement(s)** : R43: May cause sensitization by skin contact.  
R36/38: Irritating to eyes and skin.

### 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)

**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 and water.  
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

**Storage** : P103: Read label before use.

**Disposal** : P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003)

### 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

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008 [CLP]
Bis-GMA	1565-94-2	216-367-7	< 60	Xi; R22; R36/37/38	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2B; Skin Sens.,Cat. 1; H315; H317; H319
TEGDMA	109-16-0	203-652-6	< 40	Not classified	Skin Sens.,Cat. 1B; H317
BHT	128-37-0	204-881-4	< 1	N; R50/53	Aquatic Chronic,Cat. 1; H410
Titanium Dioxide	13463-67-7	236-675-5	< 1	Xi; R36/37/38; R22	Not classified

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

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### 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** : 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.
- Inhalation** : None expected for this product.

#### 4.3. Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Not Applicable

### 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** : Not Applicable
- Additional information** : Refer particularly to local circumstances and regulations.

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**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

Control Parameters	Exposure Limits
TLV Inhalable fraction & vapour	2mg/m <sup>3</sup>
MAK Inhalable fraction	20mg/m <sup>3</sup>
OSHA PEL	none
NIOSH REL	TWA 10mg/m <sup>3</sup>
ACGIH TLV	10mg/m <sup>3</sup>

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

Alberta	10mg/m <sup>3</sup> TWA
British Columbia	2mg/m <sup>3</sup> TWA aerosol, inhalable, and vapour
Ontario	2mg/m <sup>3</sup> TWA inhalable fraction and vapour
Quebec	10mg/m <sup>3</sup> STEV

Titanium Dioxide CAS: 13463-67-7

Control Parameters	Exposure Limits
NIOSH REL	Ca See Appendix A
OSHA PEL General Industry	15 mg/m <sup>3</sup> TWA
OSHA PEL Maritime	15 mg/m <sup>3</sup> TWA
ACGIH TLV	10 mg/m <sup>3</sup> TWA

**8.2. Exposure controls**

**Eye/face protection** : Wear eye protection  
**Skin protection** : Wear suitable protective clothing and gloves.

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**Respiratory protection** : Good general ventilation should be sufficient to control airborne levels.

### SECTION 9: Physical and chemical properties

#### 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

**Percent volatile** : Not Determined

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

**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 LD<sub>50</sub>** : > 2100 mg/kg(mouse/rat/hamster)

**Notes** : ~90% of the mixture consists of components of unknown toxicity (dermal)

**Oral LD<sub>50</sub>** : > 5100 mg/kg (Rat)

**Notes** : ~81% of the mixture consists of components of unknown toxicity (oral).

**Inhalation LC<sub>50</sub>** : Not able to calculate ATE mix (inhalation) due to lack of data on the components.

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

### SECTION 12: Ecological information

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**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**

**Disposal method** : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**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

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### 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** : BHT has been classified as a group 3 (Not classifiable as to its carcinogenicity to humans.), per IARC Monographs.  
Titanium Dioxide has been classified as a group 2B (possible human carcinogen), per IARC Monographs. However this product offers a low possibility of inhalation since it is not a powder or dried form.  
This product is not considered dangerous for transportation.

### SECTION 16: Other information

**Relevant R-phrases and/or H-statements (number and full text)** : R22: Harmful if swallowed.  
R36/37/38: Irritating to eyes, respiratory system and skin.  
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
Aquatic Chronic, Cat. 1: Chronic Hazards to the Aquatic Environment, Category 1  
Eye Irr., Cat. 2B: Eye Irritation, Category 2B  
Skin Irr., Cat. 2: Skin Irritation, Category 2  
Skin Sens., Cat. 1B: Skin Sensitization, Category 1B  
Skin Sens., Cat. 1: Skin Sensitization, Category 1  
H315: Causes skin irritation.  
H317: May cause an allergic skin reaction.  
H319: Causes serious eye irritation.  
H410: Very toxic to aquatic life with long lasting effects.

**Prepared by** : Anu Kattoju

**Revision summary** : This SDS replaces the 04/16/2015 SDS. Revised: **Section 1:** MSDS No, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 3:** Wt.%. **Section 4:** INHALATION, SIGNS AND SYMPTOMS OF OVEREXPOSURE - EYES. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** WATER SPILL. **Section 7:** GENERAL PROCEDURES. **Section 8:** . **Section 9:** pH, SPECIFIC GRAVITY. **Section 11:** ACUTE ( DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat) ACUTE, COMMENTS, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL

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(UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **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.