

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 01/11/2006

SDS No : 1-001.11

Date Revised : 04/16/2015

Revision No : 10

Amelogen® Plus**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : GQ/71132,GZ/72638, HD/71137,HL/71138, HQ/71139, HR/71140, HS/71141, HU/71142, MQ/71143,MR/71144, MS/71146, 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

Distributor

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 : Eye Irritation
Skin Sensitization

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : Xi



Irritant

R&S statement(s) : R43: May cause sensitization by skin contact.

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

ULTRADENT
 PRODUCTS, INC.

Date Issued : 01/11/2006
 SDS No : 1-001.11
 Date Revised : 04/16/2015
 Revision No : 10

Amelogen® Plus

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)

: H317: May cause an allergic skin reaction.
 H319: Causes serious eye irritation.

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.
 P313: Get medical advice/attention.
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.
 P332+P313: If skin irritation occurs: Get medical advice/attention.

Storage

: P103: Read label before use.

Disposal

: P501: Dispose of in compliance with governmental regulation(EC 1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns

: Irritating to eyes.

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	< 15	Xi; R36/37/38; R22	H302; H317; H318; H315; H335; H412
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 10	Xi; R43	H317

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

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



Date Issued : 01/11/2006
SDS No : 1-001.11
Date Revised : 04/16/2015
Revision No : 10

Amelogen® Plus

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. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

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** : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

- Explosion hazards** : Not Determined
- Fire explosion** : Not Determined
- Sensitive to static discharge** : Not Determined
- Sensitivity to impact** : Not Determined

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.
- Fire fighting equipment** : Foam, carbon dioxide, or water spray

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** : Not Applicable

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



Date Issued : 01/11/2006
SDS No : 1-001.11
Date Revised : 04/16/2015
Revision No : 10

Amelogen® Plus

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.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- 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** : Not Determined

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state** : Viscous paste
- Colour** : Shade dependent.
- Odour** : Acrylic

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

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 01/11/2006

SDS No : 1-001.11

Date Revised : 04/16/2015

Revision No : 10

Amelogen® Plus**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****Notes** : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.**SECTION 12: Ecological information****12.1. Toxicity****Aquatic toxicity (acute)****96-hour LC₅₀** : Not Determined**48-hour EC₅₀** : Not Determined**96-hour EC₅₀** : Not Determined**12.2. Persistence and degradability****Persistence and degradability** : Not Determined**12.3. Bioaccumulative potential****Bioaccumulative potential** : Not Determined**12.4. Mobility in soil****Mobility in soil** : Not Determined**12.5. Results of PBT and vPvB assessment****Results of PBT and vPvB assessment** : Not Determined**12.6. Other adverse effects****Environmental data** : Not defined**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Disposal method** : Dispose of in compliance with governmental regulation.(EC

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



Date Issued : 01/11/2006
 SDS No : 1-001.11
 Date Revised : 04/16/2015
 Revision No : 10

Amelogen® Plus

1975L0442-20/11/2003)

SECTION 14: Transport information

14.1. UN number

UN number : N/A

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : N/A

14.4. Packing group

Packing group : N/A

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : Not Dangerous Goods

RID - rail : Not Dangerous Goods

IMDG - sea : Not Dangerous Goods

IATA - air : Not Dangerous Goods

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

Transport in bulk : Not Dangerous Goods

SECTION 15: Regulatory information

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

RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

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.
 R43: May cause sensitization by skin contact.
 H302: Harmful if swallowed.
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H318: Causes serious eye damage.
 H335: May cause respiratory irritation.
 H412: Harmful to aquatic life with long lasting effects.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 08/20/2013 SDS. Revised: **Section 1:**

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 01/11/2006

SDS No : 1-001.11

Date Revised : 04/16/2015

Revision No : 10

Amelogen® Plus

GENERAL USE, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 3:** Wt.%. **Section 4:** INGESTION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INHALATION, SKIN). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** GENERAL PROCEDURES, WATER SPILL, . **Section 7:** SHELF LIFE, STORAGE, STORAGE TEMPERATURE, . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT (EYES AND FACE), . **Section 9:** PERCENT VOLATILE. **Section 10:** CONDITIONS TO AVOID, HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABILITY, STABLE. **Section 11:** ACUTE. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, GENERAL COMMENTS, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14:** AIR (ICAO/IATA) - SPECIAL PROVISIONS ROAD AND RAIL (ADR/RID), ROAD AND RAIL (ADR/RID) (PROPER SHIPPING NAME, UN NUMBER, PACKING GROUP), VESSEL (IMO/IMDG) (SPECIAL PROVISIONS), ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information. **Section 15:** RoHS, SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.

General statements

: N/A= Not Applicable

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.