

SAFETY DATA SHEET

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

ULTRADENT
PRODUCTS, INC.

Date Issued : 01/11/2006
SDS No : 1-001.13
Date Revised : 03/07/2018
Revision No : 12

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)

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



Date Issued : 01/11/2006
SDS No : 1-001.13
Date Revised : 03/07/2018
Revision No : 12

Amelogen® Plus

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 : 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 Regulation(EC) No 1272/2008 [CLP]
Bis-GMA	1565-94-2	216-367-7	< 60	H315; H317; H319
TEGDMA	109-16-0	203-652-6	< 40	Skin Sens.,Cat. 1B; H317
BHT	128-37-0	204-881-4	< 1	Aquatic Chronic,Cat. 1; H410
Barium aluminosilicate glass powder	65997-17-3	NAP	< 35	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2B; STOT SE,Cat. 3; H315; H319; H335

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.

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



Date Issued : 01/11/2006
 SDS No : 1-001.13
 Date Revised : 03/07/2018
 Revision No : 12

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



Date Issued : 01/11/2006

SDS No : 1-001.13

Date Revised : 03/07/2018

Revision No : 12

Amelogen® Plus

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

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

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

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.

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

- Additional information** : No further relevant information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

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



Date Issued : 01/11/2006
SDS No : 1-001.13
Date Revised : 03/07/2018
Revision No : 12

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

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



Date Issued : 01/11/2006
SDS No : 1-001.13
Date Revised : 03/07/2018
Revision No : 12

Amelogen® Plus

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

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 : Aquatic Chronic, Cat. 1: Chronic Hazards to the Aquatic Environment, Category

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



Date Issued : 01/11/2006
 SDS No : 1-001.13
 Date Revised : 03/07/2018
 Revision No : 12

Amelogen® Plus

full-text)	<p>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.</p>
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.