

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/16/2021

Reviewed on 08/20/2021

1 Identification

- **Product identifier**
- **Trade name:** Amelogen™ Plus
- **Article number:** SDS I-001.14
- **Application of the substance / the mixture** Professional Dental Composite
- **Details of the supplier of the safety data sheet**
- **Information department:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS08 Health hazard

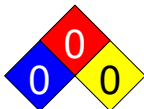
Carc. 2 H351 Suspected of causing cancer. Route of exposure: Inhalation.



GHS07

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

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** GHS07, GHS08
- **Signal word** Warning
- **Health Hazard-determining components of labeling:**
Triethylene Glycol Dimethacrylate
- **Hazard statements**
May cause an allergic skin reaction.
Suspected of causing cancer. Route of exposure: Inhalation.
- **Precautionary statements**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dust/fume/gas/mist/vapors/spray
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 If on skin: Wash with plenty of water.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P321 Specific treatment (see on this label).
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/16/2021

Reviewed on 08/20/2021

Trade name: Amelogen™ Plus

(Contd. of page 1)

· **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

109-16-0	Triethylene Glycol Dimethacrylate	⚠ Skin Sens. 1, H317	1-10%
12737-27-8	Chromium Iron Oxide		1-10%
1332-37-2	Red Iron Oxide		1-10%
658084-52-5	Lumilux Blue LZ		1-10%
13463-67-7	Titanium Dioxide	⚠ Carc. 2, H351	≥0.1-<25%

4 First-aid measures

- **Description of first aid measures**
- **After inhalation:**
This product is a thick paste, therefore inhalation is extremely unlikely.
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **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 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Water spray
Foam
Carbon dioxide
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **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.

(Contd. on page 3)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/16/2021

Reviewed on 08/20/2021

Trade name: Amelogen™ Plus

(Contd. of page 2)

- **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.
Open and handle receptacle with care.
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** Keep respiratory protective device available.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **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
Keep receptacle tightly sealed.
- **Specific end use(s)** Professional Dental Composite

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the remaining constituent has no known exposure limits.

12737-27-8 Chromium Iron Oxide

TWA	Short-term value: 0.5 mg/m ³ ACGIH, OSHA Z-1, NIOSH REL
-----	---

1332-37-2 Red Iron Oxide

ACGIH	Short-term value: 10 mg/m ³
REL	Long-term value: 1 mg/m ³ as Fe
TLV	Long-term value: 1 mg/m ³ as Fe

658084-52-5 Lumilux Blue LZ

TWA	Short-term value: 10* 3* mg/m ³
-----	--

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/16/2021

Reviewed on 08/20/2021

Trade name: Amelogen™ Plus

(Contd. of page 3)

13463-67-7 Titanium Dioxide

ACGIH TLV	Short-term value: 10* 5 mg/m ³
PEL	Long-term value: 15* mg/m ³ *total dust
REL	See Pocket Guide App. A
TLV	Long-term value: 10 mg/m ³
TWA	Short-term value: 15* 5 mg/m ³

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Store protective clothing separately.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **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 is based 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**

· **General Information**

· **Appearance:**

Form: Paste

Color: According to product specification

· **Odor:** Acrylic

· **Odor threshold:** Not determined.

· **pH-value:** Not applicable (non-aqueous)

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/16/2021

Reviewed on 08/20/2021

Trade name: Amelogen™ Plus

(Contd. of page 4)

· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined
· Flash point:	Not applicable
· Flammability (solid, gaseous):	Not applicable.
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density:	Not determined
· Relative density	Not determined
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· 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 content:	0.00 % 0.0 g/l / 0.00 lb/gal
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

US

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/16/2021

Reviewed on 08/20/2021

Trade name: Amelogen™ Plus

(Contd. of page 5)

11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

109-16-0 Triethylene Glycol Dimethacrylate

Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (mouse)

658084-52-5 Lumilux Blue LZ

Oral	LD50	>20,000 mg/kg (rat)
------	------	---------------------

13463-67-7 Titanium Dioxide

Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)

- **Primary irritant effect:**

- **on the skin:** No irritant effect.

- **on the eye:** No irritating effect.

- **Sensitization:** Sensitization possible through skin contact.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

128-37-0	Butylated Hydroxytoluene	3
----------	--------------------------	---

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

109-16-0 Triethylene Glycol Dimethacrylate

EC50	>100 mg/kg (Algae)
Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)

13463-67-7 Titanium Dioxide

EC50	>100 mg/kg (Algae)
	>1,000 mg/kg (Fish)

- **Persistence and degradability** No further relevant information available.

- **Behavior in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.

- **Mobility in soil** No further relevant information available.

(Contd. on page 7)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/16/2021

Reviewed on 08/20/2021

Trade name: Amelogen™ Plus

(Contd. of page 6)

- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (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.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT, IMDG, IATA | Not Regulated |
| · UN proper shipping name | |
| · DOT, IMDG, IATA | Not Regulated |
| · Transport hazard class(es) | |
| · DOT, ADN, IMDG, IATA | |
| · Class | Not Regulated |
| · Packing group | |
| · DOT, IMDG, IATA | Not Regulated |
| · Environmental hazards: | Not Applicable. |
| · Special precautions for user | Not Applicable |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not Applicable. |
| · UN "Model Regulation": | Not Regulated |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **Sara**

· Section 355 (extremely hazardous substances):
--

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):
--

1344-28-1 Aluminium Oxide

(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/16/2021

Reviewed on 08/20/2021

Trade name: Amelogen™ Plus

(Contd. of page 7)

· TSCA (Toxic Substances Control Act):		
109-16-0	Triethylene Glycol Dimethacrylate	ACTIVE
12737-27-8	Chromium Iron Oxide	ACTIVE
1332-37-2	Red Iron Oxide	ACTIVE
13463-67-7	Titanium Dioxide	ACTIVE
· Hazardous Air Pollutants		
None of the ingredients is listed.		
· Proposition 65		
· Chemicals known to cause cancer:		
None of the ingredients is listed.		
· Chemicals known to cause reproductive toxicity for females:		
None of the ingredients is listed.		
· Chemicals known to cause reproductive toxicity for males:		
None of the ingredients is listed.		
· Chemicals known to cause developmental toxicity:		
None of the ingredients is listed.		
· Carcinogenic categories		
· EPA (Environmental Protection Agency)		
None of the ingredients is listed.		
· ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)		
1344-28-1	Aluminium Oxide	A4
128-37-0	Butylated Hydroxytoluene	A4
· NIOSH-Ca (National Institute for Occupational Safety and Health)		
None of the ingredients is listed.		
· 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.

- **Department issuing SDS:** Environmental, Health, and Safety
- **Contact:** Customer Service
- **Date of preparation / last revision** 09/16/2021 / -
- **Abbreviations and acronyms:**
 - IMDG: International Maritime Code for Dangerous Goods
 - DOT: US Department of Transportation
 - IATA: International Air Transport Association
 - 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)
 - NFPA: National Fire Protection Association (USA)
 - HMIS: Hazardous Materials Identification System (USA)
 - 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
 - NIOSH: National Institute for Occupational Safety
 - OSHA: Occupational Safety & Health

(Contd. on page 9)

US

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/16/2021

Reviewed on 08/20/2021

Trade name: Amelogen™ Plus

(Contd. of page 8)

*TLV: Threshold Limit Value**PEL: Permissible Exposure Limit**REL: Recommended Exposure Limit**Skin Sens. 1: Skin sensitisation – Category 1**Carc. 2: Carcinogenicity – Category 2*

US