



Safety Data Sheet acc. to OSHA HCS

Printing date 02/13/2025

Reviewed on 02/13/2025

1 Identification

- **Product identifier**
- **Trade name:** Amelogen™ Plus
- **Article number:**
SDS 1-001.15R01, 72638, 71132, 71137, 71138, 71139, 71140, 71141, 71142, 71143, 71144, 71146, 71147, 71148, 71150, 71151, 71152, 71153, 71154, 71155, 71157, 71158
- **Application of the substance / the mixture** Professional Dental Composite
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com
- **Information department:**
Customer Service
Not applicable
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS07

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Health Hazard-determining components of labeling:**
Triethylene Glycol Dimethacrylate
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **Precautionary statements**
 - 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.
 - P302+P352 If on skin: Wash with plenty of water.
 - P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 - P321 Specific treatment (see on this label).
 - P363 Wash contaminated clothing before reuse.
 - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **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	≥1-≤10%
	Chromium Iron Oxide	≥0-≤10%
1332-37-2	Red Iron Oxide	≥0-≤10%
	Trade Secret	≥0-≤10%

- **Additional information:**

The specific chemical identity of composition is being withheld as a trade secret. The specific chemical identity is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of paragraph §1910.1200.

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.

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- **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.
- **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 section 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.
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** No special measures required.
- **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
- **Specific end use(s)** Professional Dental Composite

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 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.

Chromium Iron Oxide

TWA	Short-term value: 0.5 mg/m ³ ACGIH, OSHA Z-1, NIOSH REL
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1332-37-2 Red Iron Oxide

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

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

· **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)

· **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined

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· Flash point:	Not applicable
· Flammability:	Not applicable.
· Decomposition temperature:	Not determined.
· Ignition temperature:	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
· 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

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)

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Trade Secret

Oral	LD50	>20,000 mg/kg (rat)
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- **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
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· **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)
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Biodegradability	28 days (Aerobic) (Biodegradability testing)
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Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)
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- **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.
- **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:**

Dispose of contents/container in accordance with international, federal, state, and local regulations.

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- **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):**

Trade Secret

- **TSCA (Toxic Substances Control Act):**

109-16-0	Triethylene Glycol Dimethacrylate	ACTIVE
	Chromium Iron Oxide	ACTIVE
1332-37-2	Red Iron Oxide	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.

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· 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)

	Trade Secret	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 02/13/2025 / -

· 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)

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

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Sensitization - Skin 1: Skin sensitisation – Category 1

· * Data compared to the previous version altered.