



Safety data sheet according to UK REACH

Printing date 07.03.2025

Version number 1

Revision: 07.03.2025

1 Identification of the substance/mixture and of the company/undertaking

· **Product identifier**

· **Trade name:** Amelogen™ Plus

· **Article number:**

SDS I-001.15R01, 72638, 71132, 71137, 71138, 71139, 71140, 71141, 71142, 71143, 71144, 71146, 71147, 71148, 71150, 71151, 71152, 71153, 71154, 71155, 71157, 71158

· **Relevant identified uses of the substance or mixture and uses advised against** Professional Dental Composite

· **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

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

· **Further information obtainable from:**

Customer Service
Not applicable

· **Emergency telephone number:**

CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



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

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** GHS07
- **Signal word** Warning

· **Hazard-determining components of labelling:**

Triethylene Glycol Dimethacrylate

· **Hazard statements**

H317 May cause an allergic skin reaction.

· **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.

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- P103 Read carefully and follow all instructions.
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves.
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P321 Specific treatment (see on this label).
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 109-16-0 EINECS: 203-652-6	Triethylene Glycol Dimethacrylate	⚠ Skin Sens. 1, H317	≥1-≤10%
CAS: 13463-67-7 EINECS: 236-675-5	Titanium Dioxide	⚠ Carc. 2, H351	≥0.1<2.5%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- **Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **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.
- **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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
 Water spray
 Foam
 Carbon dioxide
 Use fire extinguishing methods suitable to surrounding conditions.
- **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.

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- **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

- **Precautions for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** 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

- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**

13463-67-7 Titanium Dioxide

WEL	Long-term value: 10* 4** mg/m ³ *total inhalable **respirable
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- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as 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.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Hand protection**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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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 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/face protection** Goggles recommended during refilling

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Physical state**

Fluid

· **Colour:**

According to product specification

· **Odour:**

Acrylic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range**

Undetermined.

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

Not applicable.

· **Decomposition temperature:**

Not determined.

· **pH**

Not applicable (non-aqueous)

· **Viscosity:**

· **Kinematic viscosity**

Not determined.

· **Dynamic:**

Not determined.

· **Solubility**

· **water:**

Not miscible or difficult to mix.

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure:**

Not determined.

· **Density and/or relative density**

· **Density:**

Not determined.

· **Relative density**

Not determined.

· **Vapour density**

Not determined.

· **Other information**

· **Appearance:**

· **Form:**

Paste

· **Important information on protection of health and environment, and on safety.**

· **Ignition temperature:**

Product is not selfigniting.

· **Explosive properties:**

Product does not present an explosion hazard.

· **Change in condition**

· **Evaporation rate**

Not determined.

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· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· LD/LC50 values 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)

13463-67-7 Titanium Dioxide

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

- **Respiratory or skin sensitisation** May cause an allergic skin reaction.

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· Information on other hazards

· Endocrine disrupting properties

128-37-0 Butylated Hydroxytoluene

List II

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.· **Bioaccumulative potential** No further relevant information available.· **Mobility in soil** No further relevant information available.

· Results of PBT and vPvB assessment

· **PBT:** Not applicable.· **vPvB:** Not applicable.· **Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.· **Other adverse effects**

· Additional ecological information:

· General notes:

Water hazard class 1 (German Regulation) (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.

13 Disposal considerations

· Waste treatment methods

· Recommendation

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

· Uncleaned packaging:

· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN number or ID number

· ADR, IMDG, IATA

not regulated

· UN proper shipping name

· ADR, ADN, IMDG, IATA

not regulated

· Transport hazard class(es)

· ADR, ADN, IMDG, IATA

· Class

not regulated

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- | | |
|--|-----------------|
| · Packing group | not regulated |
| · ADR, IMDG, IATA | not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not Applicable |
| · Maritime transport in bulk according to IMO instruments | Not applicable. |
| · UN "Model Regulation": | not regulated |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **Poisons Act**

- **Regulated explosives precursors**

None of the ingredients is listed.

- **Regulated poisons**

None of the ingredients is listed.

- **Reportable explosives precursors**

None of the ingredients is listed.

- **Reportable poisons**

None of the ingredients is listed.

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** 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.

- **Relevant phrases from Section 3**

H317 May cause an allergic skin reaction.

H351 Suspected of causing cancer.

- **Department issuing SDS:** Environmental, Health, and Safety

- **Contact:** Customer Service

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
ATE: Acute toxicity estimate values
Skin Sens. 1: Skin sensitisation – Category 1
Carc. 2: Carcinogenicity – Category 2

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