



Safety Data Sheet according to WHS Regulations

Date of issue: 07.03.2025

Revision: 07.03.2025

*

1 Identification

- **Other means of identification**
- **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
- **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

Ultradent Australia Pty Ltd.
Level 22/2 Market Street
Sydney NSW 2000
Australia
Email: info.anz@ultradent.com
Toll Free: 1-800-290929
Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com
- **Further information obtainable from:**
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**



Skin sensitisation – Category 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Triethylene Glycol Dimethacrylate (≥1-<10 %)

(Contd. on page 2)

AU

Safety Data Sheet

according to WHS Regulations

Date of issue: 07.03.2025

Revision: 07.03.2025

Trade name: Amelogen™ Plus

(Contd. of page 1)

- **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.

P103 Read label before use.

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 and Information on Ingredients

- **Chemical characterisation: Mixtures**

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

- **Dangerous components:**

109-16-0	Triethylene Glycol Dimethacrylate	⚠ Skin sensitisation – Category 1, H317	≥1-<10%
1332-37-2	Red Iron Oxide		≥0-<10%

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

4 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.

- **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

- **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.

- **Protective equipment:** Wear fully protective suit.

-AU-

(Contd. on page 3)

Safety Data Sheet

according to WHS Regulations

Date of issue: 07.03.2025

Revision: 07.03.2025

Trade name: Amelogen™ Plus

(Contd. of page 2)

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 fire - and explosion protection:** No special measures required.
- **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 and personal protection

- **Appropriate engineering controls** No further data; see section 7.
- **Ingredients with limit values that require monitoring at the workplace:**

1332-37-2 Red Iron Oxide

WES	Long-term value: 1 mg/m ³ as Fe
-----	---

- **Additional information:** The lists valid during the making were used as basis.
- **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.
- **Protection of hands:**



Protective gloves

(Contd. on page 4)

Safety Data Sheet

according to WHS Regulations

Date of issue: 07.03.2025

Revision: 07.03.2025

Trade name: Amelogen™ Plus

(Contd. of page 3)

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 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

- **General Information**

- **Appearance:**

- **Form:**

Paste

- **Colour:**

According to product specification

- **Odour:**

Acrylic

- **Odour threshold:**

Not determined.

- **pH-value:**

Not applicable (non-aqueous)

- **Change in condition**

- **Melting point/freezing point:**

Undetermined.

- **Initial boiling point and boiling range:**

Undetermined.

- **Flash point:**

Not applicable.

- **Flammability**

Not applicable.

- **Decomposition temperature:**

Not determined.

- **Ignition temperature:**

Product is not selfigniting.

- **Explosive properties:**

Product does not present an explosion hazard.

- **Explosion limits:**

- **Lower:**

Not determined.

- **Upper:**

Not determined.

- **Vapour pressure:**

Not determined.

- **Density:**

Not determined.

- **Relative density**

Not determined.

- **Vapour 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**

- **Particle characteristics**

Not applicable.

- **Physical state**

Fluid

AU

(Contd. on page 5)

Safety Data Sheet

according to WHS Regulations

Date of issue: 07.03.2025

Revision: 07.03.2025

Trade name: Amelogen™ Plus

(Contd. of page 4)

10 Stability and Reactivity

- **Reactivity** Polymerization under the influence of light.
- **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** 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)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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)

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

(Contd. on page 6)

Safety Data Sheet

according to WHS Regulations

Date of issue: 07.03.2025

Revision: 07.03.2025

Trade name: Amelogen™ Plus

(Contd. of page 5)

- **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.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|---|-----------------|
| · UN-Number | |
| · ADG, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · ADG, IMDG, IATA | not regulated |
| · Transport hazard class(es) | |
| · ADG, ADN, IMDG, IATA | |
| · Class | not regulated |
| · Packing group | |
| · ADG, IMDG, IATA | not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not Applicable |
| · Transport in bulk according to Annex II of Marpol 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**

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

None of the ingredients is listed.

- **Australian Inventory of Industrial Chemicals**

	Trade Secret
109-16-0	Triethylene Glycol Dimethacrylate
	Chromium Iron Oxide
1332-37-2	Red Iron Oxide
51274-00-1	Yellow Iron Oxide
13463-67-7	Titanium Dioxide
128-37-0	Butylated Hydroxytoluene

(Contd. on page 7)

Safety Data Sheet

according to WHS Regulations

Date of issue: 07.03.2025

Revision: 07.03.2025

Trade name: Amelogen™ Plus

(Contd. of page 6)

10287-53-3 Ethyl-4-Dimethylamino Benzoate

10373-78-1 Camphorquinone

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Australia: Priority Existing Chemicals**

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.

· **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

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

Skin sensitisation – Category 1: Skin sensitisation – Category 1

· *** Data compared to the previous version altered.**

AU