

## Safety Data Sheet

according to WHS Regulations

Printing date 27.07.2023

Revision: 27.07.2023

### 1 Identification

- **Product identifier**
- **Trade name:** Amelogen™ Plus
- **Article number:**  
SDS 1-001.14R02, 71138, 71140, 71141, 71142, 71143, 71144, 71147, 71148, 71150, 71151, 71152, 71153, 71154, 71155, 71157, 71158, 72638.
- **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  
Email: info.anz@ultradent.com  
Toll Free: 1-800-290929  
None
- **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 Sens. 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
- **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.

(Contd. on page 2)

# Safety Data Sheet

## according to WHS Regulations

Printing date 27.07.2023

Revision: 27.07.2023

**Trade name: Amelogen™ Plus**

(Contd. of page 1)

- 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 Sens. 1, H317	≥1-<10%
1332-37-2	Red Iron Oxide		<10%
13463-67-7	Titanium Dioxide	⚠ Carc. 2, H351	≥0.1-<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.

### 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).

(Contd. on page 3)

# Safety Data Sheet

## according to WHS Regulations

Printing date 27.07.2023

Revision: 27.07.2023

**Trade name: Amelogen™ Plus**

(Contd. of page 2)

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.

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

· **Additional information about design of technical facilities:** No further data; see item 7.

· **Ingredients with limit values that require monitoring at the workplace:**

**1332-37-2 Red Iron Oxide**

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

**13463-67-7 Titanium Dioxide**

WES	Long-term value: 10 mg/m <sup>3</sup> inhalable dust
-----	---

· **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

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

(Contd. on page 4)

# Safety Data Sheet

## according to WHS Regulations

Printing date 27.07.2023

Revision: 27.07.2023

Trade name: Amelogen™ Plus

(Contd. of page 3)

- **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 (solid, gas):**

Not applicable.

- **Decomposition temperature:**

Not determined.

- **Auto-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**

No further relevant information available.

## 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

(Contd. on page 5)

# Safety Data Sheet

## according to WHS Regulations

Printing date 27.07.2023

Revision: 27.07.2023

Trade name: Amelogen™ Plus

(Contd. of page 4)

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)

#### 13463-67-7 Titanium Dioxide

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

- **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)

#### 13463-67-7 Titanium Dioxide

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

- **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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

(Contd. on page 6)

# Safety Data Sheet

## according to WHS Regulations

Printing date 27.07.2023

Revision: 27.07.2023

Trade name: Amelogen™ Plus

(Contd. of page 5)

· **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

· <b>UN-Number</b>	
· <b>ADG, IMDG, IATA</b>	not regulated
· <b>UN proper shipping name</b>	
· <b>ADG, IMDG, IATA</b>	not regulated
· <b>Transport hazard class(es)</b>	
· <b>ADG, ADN, IMDG, IATA</b>	
· <b>Class</b>	not regulated
· <b>Packing group</b>	
· <b>ADG, IMDG, IATA</b>	not regulated
· <b>Environmental hazards:</b>	Not applicable.
· <b>Special precautions for user</b>	Not Applicable
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	not regulated

### 15 Regulatory information

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

· <b>Australian Inventory of Industrial Chemicals</b>	
	Trade Secret
109-16-0	Triethylene Glycol Dimethacrylate
12737-27-8	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
10287-53-3	Ethyl-4-Dimethylamino Benzoate
10373-78-1	Camphorquinone
· <b>Standard for the Uniform Scheduling of Medicines and Poisons</b>	
None of the ingredients is listed.	

(Contd. on page 7)

# Safety Data Sheet

## according to WHS Regulations

Printing date 27.07.2023

Revision: 27.07.2023

Trade name: Amelogen™ Plus

(Contd. of page 6)

· **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.

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

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

Skin Sens. 1: Skin sensitisation – Category 1

Carc. 2: Carcinogenicity – Category 2

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

-AU-