

Safety Data Sheet

according to WHS Regulations

Printing date 28.07.2023

Revision: 28.07.2023

1 Identification

- **Product identifier**
- **Trade name:** *UltraSeal XT™ plus*
- **Article number:** SDS 25-001.16R02, 13560, 56303, 10952, 73401
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Pit and Fissure Sealant
- **Application of the substance / the mixture** *Professional Dental Pit and Fissure Sealant*
- **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*
- **Further information obtainable from:** *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**



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
Diurethane 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.*
 - P103 Read label before use.*
 - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.*

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- 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	10-<30%
	⚠ Skin Sens. 1, H317	
72869-86-4	Diurethane Dimethacrylate	10-<30%
	⚠ Skin Sens. 1, H317	
	Trade Secret	≥5-<10%
	⚠ Skin Corr. 1A, H314; Eye Dam. 1, H318	
	Trade Secret	<10%
79-41-4	Methacrylic Acid	<1%
	⚠ Acute Tox. 3, H331; ⚠ Skin Corr. 1A, H314; Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Flam. Liq. 4, H227	
13463-67-7	Titanium Dioxide	≥0.1-<10%
	⚠ Carc. 2, H351	
162881-26-7	Organophosphine Oxide	≥0.1-<1%
	⚠ Skin Sens. 1, H317	

- **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:**
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 swallowed in large quantities seek medical attention.
- **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:**
Foam, dry chemical, carbon dioxide
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.

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· **Protective equipment:** No special measures required.

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:**
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:**
Avoid contact with eyes, skin, and clothing. Use suitable protective equipment.
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** See product labeling.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** See product labelling.
- **Specific end use(s)** Professional Dental Pit and Fissure Sealant

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:**

Trade Secret

WES	Long-term value: 10 mg/m ³ inhalable dust
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79-41-4 Methacrylic Acid

WES	Long-term value: 70 mg/m ³ , 20 ppm
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13463-67-7 Titanium Dioxide

WES	Long-term value: 10 mg/m ³ inhalable dust
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- **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.

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· 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

· 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:** Not required.

· **Body protection:** Protective work clothing

9 Physical and Chemical Properties

· General Information**· Appearance:**

- **Form:** Liquid
- **Colour:** Shade dependent
- **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:** >100 °C
- **Flammability (solid, gas):** Not determined.
- **Ignition temperature:** 445 °C
- **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 at 20 °C:** 0 hPa
- **Density at 20 °C:** 1.7-1.8 g/cm³
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with**
- **water:** Insoluble.
- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
- **Dynamic:** Not applicable.
- **Kinematic:** Not applicable.

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· **Other information**

No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** Avoid light exposure
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

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)

72869-86-4 Diurethane Dimethacrylate

Oral	LD50	>5,000 mg/kg (rat)
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Trade Secret

Oral	LD50	>5,000 mg/kg (rat)
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79-41-4 Methacrylic Acid

Oral	LD50	1,250 mg/kg (mouse) 1,060 mg/kg (rat) 1,200 mg/kg (rabbit)
	LC50 Fish	86 mg/l (Fish)
Dermal	LD50	1,000 mg/kg (Guinea pig) 500 mg/kg (rabbit)
Inhalative	LC50/4 h	7.1 mg/l (rat)

13463-67-7 Titanium Dioxide

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

162881-26-7 Organophosphine Oxide

Oral	LD50	>2,000 mg/kg (rat)
	LC50 Fish	>0.09 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (rat)

- **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.

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- **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)

72869-86-4 Diurethane Dimethacrylate

EC50	>0.6 mg/kg (Algae)
Biodegradability	28 days (Aerobic) (Biodegradability testing)

79-41-4 Methacrylic Acid

EC50	17,000 mg/kg (Algae)
	<180 mg/kg (daphnia) (Toxicity to aquatic invertebrates)

13463-67-7 Titanium Dioxide

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

162881-26-7 Organophosphine Oxide

EC50 (static)	>1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
Aqua toxicity	≥0.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)
Toxicity to Aquatic Plants (static)	>0.26 mg/l (Plant) (Toxicity to algae)

- **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.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.
 Dispose of contents/container in accordance with international, federal, state, and local regulations.

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

14 Transport information

· UN-Number	
· ADG, ADN, IMDG, IATA	not regulated
· UN proper shipping name	
· ADG, ADN, 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	
· Australian Inventory of Industrial Chemicals	
109-16-0	Triethylene Glycol Dimethacrylate
72869-86-4	Diurethane Dimethacrylate
	Trade Secret
3290-92-4	TMPTMA
79-41-4	Methacrylic Acid
13463-67-7	Titanium Dioxide
10287-53-3	Ethyl-4-Dimethylamino Benzoate
10373-78-1	Camphorquinone
162881-26-7	Organophosphine Oxide
10163-15-2	Sodium Monofluorophosphate
1332-37-2	Red Iron Oxide
51274-00-1	Yellow Iron Oxide
12737-27-8	Chromium Iron Oxide
· 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.	

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- **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**

H227 Combustible liquid.
H302 Harmful if swallowed.
H312 Harmful in contact with skin.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H331 Toxic if inhaled.
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
Flam. Liq. 4: Flammable liquids – Category 4
Acute Tox. 4: Acute toxicity – Category 4
Acute Tox. 3: Acute toxicity – Category 3
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Carc. 2: Carcinogenicity – Category 2

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

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