

Safety Data Sheet
according to WHS Regulations

Printing date 28.07.2023

Revision: 28.07.2023

1 Identification

- **Product identifier**
- **Trade name:** *UltraSeal XT™ Hydro™*
- **Article number:** SDS 239-001.10R02, 71110, 71111, 71109
- **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 ⚠ Skin Sens. 1, H317	>10-<30%
72869-86-4	Diurethane Dimethacrylate ⚠ Skin Sens. 1, H317	>5-<20%
	Trade Secret ⚠ Skin Corr. 1A, H314; Eye Dam. 1, H318	>1-<10%
13463-67-7	Titanium Dioxide ⚠ Carc. 2, H351	>1-<10%
79-41-4	Methacrylic Acid ⚠ Acute Tox. 3, H331; ⚠ Skin Corr. 1A, H314; Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Flam. Liq. 4, H227	≤1%
162881-26-7	Organophosphine Oxide ⚠ Skin Sens. 1, H317	<1%

- **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:**
 Seek medical treatment in case of complaints.
 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:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

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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 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.
- **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:**

13463-67-7 Titanium Dioxide

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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- **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.

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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 protection:** Goggles recommended during refilling

- **Body protection:** Protective work clothing

9 Physical and Chemical Properties

- **General Information**

- **Appearance:**

- **Form:**

Liquid

- **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 at 20 °C:**

1.67 g/cm³

- **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** 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.

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- **Conditions to avoid:** No further relevant information available.
- **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)
13463-67-7 Titanium Dioxide		
Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
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)
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.
- **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.

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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)
13463-67-7 Titanium Dioxide	
EC50	>100 mg/kg (Algae) >1,000 mg/kg (Fish)
79-41-4 Methacrylic Acid	
EC50	17,000 mg/kg (Algae) <180 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
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**

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

- **Uncleaned packaging:**

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

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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
13463-67-7	Titanium Dioxide
	Trade Secret
3290-92-4	TMPTMA
79-41-4	Methacrylic Acid
10287-53-3	Ethyl-4-Dimethylamino Benzoate
51274-00-1	Yellow Iron Oxide
10373-78-1	Camphorquinone
162881-26-7	Organophosphine Oxide
1332-37-2	Red Iron Oxide
10163-15-2	Sodium Monofluorophosphate
· 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	

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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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