

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 22.11.2022

Version number 1

Revision: 22.11.2022

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

- **Product identifier**
- **Trade name:** *UltraSeal XT™ Hydro™*
- **Article number:** SDS 239-001.10, 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*
- 
- 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*
- **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*  
*Diurethane Dimethacrylate*  
*Organophosphine Oxide*
- **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	>10-<30%
CAS: 72869-86-4 EINECS: 276-957-5	Diurethane Dimethacrylate ⚠ Skin Sens. 1, H317	>5-<20%
	Trade Secret ⚠ Skin Corr. 1A, H314; Eye Dam. 1, H318	>1-<10%
CAS: 13463-67-7 EINECS: 236-675-5	Titanium Dioxide ⚠ Carc. 2, H351	>1-<10%
CAS: 79-41-4 EINECS: 201-204-4	Methacrylic Acid ⚠ Acute Tox. 3, H331; ⚠ Skin Corr. 1A, H314; Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312 Specific concentration limit: STOT SE 3; H335: C ≥ 1 %	≤1%
CAS: 162881-26-7 ELINCS: 423-340-5	Organophosphine Oxide ⚠ Skin Sens. 1A, H317; Aquatic Chronic 4, H413	<1%

- **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:**  
 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.
- **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:** 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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- **Advice for firefighters:**
- **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:**  
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

- **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.
- **Specific end use(s)** Professional Dental Pit and Fissure Sealant

### 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 <sup>3</sup> *total inhalable **respirable
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#### 79-41-4 Methacrylic Acid

WEL	Short-term value: 143 mg/m <sup>3</sup> , 40 ppm Long-term value: 72 mg/m <sup>3</sup> , 20 ppm
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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 item 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.

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### · Hand protection



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/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

· <b>Physical state</b>	Fluid
· <b>Colour:</b>	According to product specification
· <b>Odour:</b>	Acrylic
· <b>Odour threshold:</b>	Not determined.
· <b>Melting point/freezing point:</b>	Undetermined.
· <b>Boiling point or initial boiling point and boiling range</b>	Undetermined.
· <b>Flammability</b>	Not applicable.
· <b>Lower and upper explosion limit</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Flash point:</b>	Not applicable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>pH</b>	Not applicable (non-aqueous)
· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not determined.
· <b>Dynamic:</b>	Not determined.
· <b>Solubility</b>	
· <b>water:</b>	Not miscible or difficult to mix.
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Vapour pressure:</b>	Not determined.
· <b>Density and/or relative density</b>	
· <b>Density at 20 °C:</b>	1.67 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.

### · Other information

· **Appearance:**

· **Form:** Liquid

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- **Important information on protection of health and environment, and on safety.**
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Change in condition**
- **Evaporation rate** Not determined.

- **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** No further relevant information available.
- **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:** 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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity**

· **LD/LC50 values relevant for classification:**

**ATE (Acute Toxicity Estimates)**

Inhalative	LC50/4 h	711 mg/l (rat)
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**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)

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**72869-86-4 Diurethane Dimethacrylate**

Oral	LD50	>5,000 mg/kg (rat)
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**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)
Dermal	LD50	86 mg/l (Fish)
		1,000 mg/kg (Guinea pig)
Inhalative	LC50/4 h	500 mg/kg (rabbit)
		7.1 mg/l (rat)

**162881-26-7 Organophosphine Oxide**

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

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

- **Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

**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)

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- **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** The product does not contain substances with endocrine disrupting properties.
- **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

· <b>UN number or ID number</b> · <b>ADR, ADN, IMDG, IATA</b>	<i>not regulated</i>
· <b>UN proper shipping name</b> · <b>ADR, ADN, IMDG, IATA</b>	<i>not regulated</i>
· <b>Transport hazard class(es)</b> · <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	<i>not regulated</i>
· <b>Packing group</b> · <b>ADR, IMDG, IATA</b>	<i>not regulated</i>
· <b>Environmental hazards:</b>	<i>Not applicable.</i>
· <b>Special precautions for user</b>	<i>Not Applicable</i>
· <b>Maritime transport in bulk according to IMO instruments</b>	<i>Not applicable.</i>
· <b>UN "Model Regulation":</b>	<i>not regulated</i>

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** *None of the ingredients is listed.*

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· **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**

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.

H413 May cause long lasting harmful effects to aquatic life.

· **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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

Skin Sens. 1A: Skin sensitisation – Category 1A

Carc. 2: Carcinogenicity – Category 2

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

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