Safety Data Sheet
acc. to OSHA HCS

Printing date 11/08/2022 Reviewed on 11/08/2022

1 Identification

· **Product identifier**

· **Trade name: UltraSeal XT™ Hydro™**

· **Article number:** SDS 239-001.10, 71110, 71111, 71109
· **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

· **Information department:** 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**

GHS07

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** GHS07
· **Signal word** Warning

· **Health Hazard-determining components of labeling:**
Triethylene Glycol Dimethacrylate
Diurethane Dimethacrylate
Organophosphine Oxide
· **Hazard statements**
H317 May cause an allergic skin reaction.
· **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapors/spray
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.
P302+P352 If on skin: Wash with plenty of water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
P363 Wash contaminated clothing before reuse.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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· **Classification system:**
· **NFPA ratings (scale 0 - 4)**

Health = 1
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = *0
Fire = 0
Reactivity = 0

*
3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**		
	Trade Secret	>40 - <60%
109-16-0	Triethylene Glycol Dimethacrylate	>10-<30%
72869-86-4	Diurethane Dimethacrylate	>5-<20%
	Trade Secret	>1-<10%
13463-67-7	Titanium Dioxide	>1-<10%
3290-92-4	TMPTMA	>1-<10%
79-41-4	Methacrylic Acid	≤1%
162881-26-7	Organophosphine Oxide	<1%

· **Additional information:**
The specific chemical identity of composition is being withheld as a trade secret. The specific chemical identity is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of paragraph §1910.1200.

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. Then consult a doctor.
· **After swallowing:** Drink copious amounts of water and provide fresh air. Immediately call a 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.

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5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture**
During heating or in case of fire poisonous gases are produced.
· **Advice for firefighters**
· **Protective equipment:** Mouth respiratory protective device.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
Wear protective equipment. Keep unprotected persons away.
· **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).
Use neutralizing agent.
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 protection against explosions and fires:** Keep respiratory protective device available.

· **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.
Keep receptacle tightly sealed.
· **Specific end use(s)** Professional Dental Pit and Fissure Sealant

8 Exposure controls/personal protection

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

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

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Trade Secret	
TWA	Short-term value: 10* 3* mg/m³
13463-67-7 Titanium Dioxide	
ACGIH TLV	Short-term value: 10* 5 mg/m³
PEL	Long-term value: 15* mg/m³ *total dust
REL	See Pocket Guide App. A
TLV	Long-term value: 0.2* 2.5** mg/m³ resp. fraction, *nanoscale,**finescale, A3
TWA	Short-term value: 15* 5 mg/m³
3290-92-4 TMPTMA	
TWA	Short-term value: 1 mg/m³
WEEL	Long-term value: 1 mg/m³ Skin
79-41-4 Methacrylic Acid	
REL	Long-term value: 70 mg/m³, 20 ppm Skin
TLV	Long-term value: 20 ppm

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes.
Avoid contact with the eyes and skin.
· **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
· **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 is based 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.

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· **Eye protection:**

Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	According to product specification
· **Odor:**	Acrylic
· **Odor threshold:**	Not determined.
· **pH-value:**	Not applicable (non-aqueous)
· **Change in condition**	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined
· **Flash point:**	Not applicable
· **Flammability (solid, gaseous):**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure:**	Not determined.
· **Density at 20 °C:**	1.67 g/cm³
· **Relative density**	Not determined
· **Vapor 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.

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· **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 toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**		
ATE (Acute Toxicity Estimate)		
Inhalative	LC50/4 h	711 mg/l (rat)

Trade Secret		
Oral	LD50	>20,000 mg/kg (rat)
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)
3290-92-4 TMPTMA		
Oral	LD50	>2,000 mg/kg (rat)
	LC50 Fish	2 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (rat) (Dermal test method)
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)

· **Primary irritant effect:**
· **on the skin:** Strong caustic effect on skin and mucous membranes.
· **on the eye:**
Strong caustic effect.

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Strong irritant with the danger of severe eye injury.
· ***Sensitization:*** *Sensitization possible through skin contact.*
· ***Additional toxicological information:***
The product shows the following dangers according to internally approved calculation methods for preparations:
Corrosive
Irritant
Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

· ***Carcinogenic categories***

· ***IARC (International Agency for Research on Cancer)***
None of the ingredients is listed.

· ***NTP (National Toxicology Program)***
None of the ingredients is listed.

· ***OSHA-Ca (Occupational Safety & Health Administration)***
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)*
3290-92-4 TMPTMA	
EC50	*>9.22 mg/kg (daphnia)*
Biodegradability	*28 days (Aerobic) (Biodegradability)*
Algae Toxicity	*0.177 mg/l (Algae) (Toxicity to algae)*
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.*
· ***Behavior in environmental systems:***
· ***Bioaccumulative potential*** *No further relevant information available.*
· ***Mobility in soil*** *No further relevant information available.*

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· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (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.
Must not reach bodies of water or drainage ditch undiluted or unneutralized.
· **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 packagings:**
· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN-Number**	
· **DOT, ADN, IMDG, IATA**	Not Regulated
· **UN proper shipping name**	
· **DOT, ADN, IMDG, IATA**	Not Regulated
· **Transport hazard class(es)**	
· **DOT, ADN, IMDG, IATA**	
· **Class**	Not Regulated
· **Packing group**	
· **DOT, IMDG, IATA**	Not Regulated
· **Environmental hazards:**	Not Applicable.
· **Special precautions for user**	Not Applicable
· **Transport in bulk according to Annex II of MARPOL73/78 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**
No further relevant information available.
· **Sara**

· **Section 355 (extremely hazardous substances):**
None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**
Trade Secret

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· **TSCA (Toxic Substances Control Act):**

13463-67-7	Titanium Dioxide	ACTIVE

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

Trade Secret	A4

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

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.

· **Department issuing SDS:** Environmental, Health, and Safety
· **Contact:** Customer Service
· **Date of preparation / last revision** 11/08/2022 / -
· **Abbreviations and acronyms:**
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
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
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Sensitization - Skin 1: Skin sensitisation – Category 1
· *** Data compared to the previous version altered.**