

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

Printing date 10.03.2020

Revision: 09.10.2018

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

- **Product identifier**
- **Trade name:** *UltraSeal XT™ Hydro™*
- **Article number:** 71109, 71110, 71111
- **Index number:** SDS 239-001.09
- **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 Westhoyer 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**
The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
- **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.

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- **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.*
- P272 *Contaminated work clothing should not be allowed out of the workplace.*
- P280 *Wear protective gloves.*
- P302+P352 *IF ON SKIN: Wash with plenty of water.*
- 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.*

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterisation: 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	≤20%
CAS: 72869-86-4 EINECS: 276-957-5	Diurethane Dimethacrylate ⚠ Skin Sens. 1, H317	<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	<5%
CAS: 162881-26-7 ELINCS: 423-340-5	Organophosphine Oxide ⚠ Skin Sens. 1, H317; Aquatic Chronic 4, H413	<1%
CAS: 10163-15-2 EINECS: 233-433-0	Sodium Monofluorophosphate ⚠ Acute Tox. 4, H302	≤0.2%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- **Description of first aid measures**

- **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.

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- **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.
- **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

- **Handling:**
- **Precautions for safe handling:** No special precautions are necessary if used correctly.
- **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

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

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

79-41-4 Methacrylic Acid

WEL (Great Britain)	Short-term value: 143 mg/m ³ , 40 ppm
	Long-term value: 72 mg/m ³ , 20 ppm

- **Additional information:** The lists valid during the making were used as basis.

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- **Exposure controls**
- **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
- **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

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Liquid
Colour:	According to product specification
Odour:	Acrylic
Odour threshold:	Not determined.
- **pH-value:** Not determined.
- **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.
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Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density at 20 °C:	1.67 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
VOC (EC)	1.00 %
· Solids content:	<80 %
· Other information	No further relevant information available.

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 toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Inhalative	LC50/4 h	711 mg/l
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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)

72869-86-4 Diurethane Dimethacrylate

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)

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Dermal	LC50 Fish	86 mg/l (Fish)
	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:**
- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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	
Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)
EC50	>100 mg/l (Algae) (Toxicity to algae)
72869-86-4 Diurethane Dimethacrylate	
Biodegradability	28 days (Aerobic) (Biodegradability testing)
EC50	>0.6 mg/l (Algae) (Toxicity to algae) >1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates)
79-41-4 Methacrylic Acid	
EC50	<180 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
EC50	45 mg/l (Algae) (Toxicity to algae)
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

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- 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.

- **European waste catalogue**

HP8	Corrosive
HP13	Sensitising

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

14 Transport information

· UN-Number	
· ADR, ADN, IMDG, IATA	not regulated
· UN proper shipping name	
· ADR, ADN, IMDG, IATA	not regulated
· Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· ADR, 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**
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **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**

- 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.
- H413 May cause long lasting harmful effects to aquatic life.

· **Department issuing SDS:** Regulatory Affairs

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

- ADR: Accord européen sur le transport 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)
- VOC: Volatile Organic Compounds (USA, EU)
- 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 - oral – Category 4
- Acute Tox. 3: Acute toxicity - inhalation – 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
- Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

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