

SAFETY DATA SHEETS

This SDS packet was issued with item:

077640105

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077640097 077640121 077640139

SAFETY DATA SHEET



Date Issued : 2/29/2012
 MSDS No : 239-001.3
 Date-Revised : 10/2/2013
 Revision No : 2

UltraSeal XT® hydro™

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

PRODUCT NAME: UltraSeal XT® hydro™
PRODUCT DESCRIPTION: Adhesive Pit and fissure sealant
PRODUCT CODE/ PART #: XI/71109, XJ/ 71110, XS/71111

MANUFACTURER

Ultradent Products, Inc.
 505 W. 10200 S.
 South Jordan, UT 84095

24 HR. EMERGENCY TELEPHONE NUMBERS

CHEMTREC (NORTH AMERICA) :(800) 424 - 9300
(INTERNATIONAL) :+1(703) 527 - 3887

2. COMPOSITION / INFORMATION ON INGREDIENTS

| Chemical Name | CAS | EINECS | Classification | Wt.% |
|-----------------------------------|------------|-----------|--------------------------|-------|
| Triethylene Glycol Dimethacrylate | 109-16-0 | 203-652-6 | Xi; R43 | <= 17 |
| Diurethane Dimethacrylate (DUDMA) | 72869-86-4 | 276-957-5 | Xi; R36/37/38 | < 8 |
| Aluminum Oxide | 1344-28-1 | 215-691-6 | Xi; R36/37 | < 4 |
| Methacrylic Acid | 79-41-4 | 201-204-4 | Xi; R36/37/38 | <= 1 |
| Titanium Dioxide | 13463-67-7 | 236-675-5 | Xi; R36/37/38, R22 | < 0.3 |
| Sodium Monofluorophosphate | 10163-15-2 | 233-433-0 | T; R22, R38 | < 0.2 |

(Full text of R-Phrases can be found under heading 16)

3. HAZARDS IDENTIFICATION

HAZARD DESIGNATION

"Xi" - Irritant
 R36: Irritating to eyes.
 R43: May cause sensitization by skin contact.

POTENTIAL HEALTH EFFECTS

EYES: May cause eye irritation.
SKIN: May cause sensitization to skin.
INGESTION: May be harmful if swallowed.
INHALATION: None Expected.

4. FIRST AID MEASURES

EYES: Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.
SKIN: Wash with soap and water. Get medical attention if irritation develops or persists.
INGESTION: Get medical attention immediately.
INHALATION: No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels

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of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

5. FIRE FIGHTING MEASURES

FIRE FIGHTING PROCEDURES: General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

FIRE FIGHTING EQUIPMENT: Foam, dry chemical, carbon dioxide (CO₂).

6. ACCIDENTAL RELEASE MEASURES

SMALL SPILL: Clean up spills immediately, observing precautions in Protective Equipment section.

LARGE SPILL: Absorb with inert, damp non-combustible material, then flush area with water.

7. HANDLING AND STORAGE

HANDLING: Use suitable protective equipment.

STORAGE: Keep refrigerated.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

PERSONAL PROTECTIVE EQUIPMENT

EYES AND FACE: Wear eye protection

SKIN: S36: Wear suitable protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: Liquid

ODOR: Acrylic

APPEARANCE: Tinted Liquid

COLOR: Dependent upon color shade

10. STABILITY AND REACTIVITY

POLYMERIZATION: Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.

CONDITIONS TO AVOID: Avoid light exposure.

11. TOXICOLOGICAL INFORMATION

EYE EFFECTS: May cause eye irritation.

SKIN EFFECTS: May cause sensitization to skin.

SENSITIZATION: Repeated or prolonged use, may cause irritation.

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL DATA: Not Available

13. DISPOSAL CONSIDERATIONS

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DISPOSAL METHOD: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

14. TRANSPORT INFORMATION

ROAD AND RAIL (ADR/RID)

LABEL: Not classified

AIR (ICAO/IATA)

LABEL: Not classified

VESSEL (IMO/IMDG)

LABEL: Not classified

15. REGULATORY INFORMATION

EUROPEAN COMMUNITY

EEC LABEL SYMBOL AND CLASSIFICATION



"Xi" - Irritant

R36: Irritating to eyes.

R43: May cause sensitization by skin contact.

COMMENTS WARNING! This product contains a chemical known to the State of California to cause cancer on the CA Prop 65 List. Titanium Dioxide.

16. OTHER INFORMATION

RELEVANT R-PHRASES: R43: May cause sensitization by skin contact.

R36/37/38: Irritating to eyes, respiratory system and skin.

R22: Harmful if swallowed.

R38: Irritating to skin.

PREPARED BY: Anu Kattoju

REVISION SUMMARY: This MSDS replaces the 11/29/2012 MSDS. Revised: **Section 1:** PREPARED BY. **Section 3:** Wt.%.

MANUFACTURER DISCLAIMER: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material MSDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.

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

Printing date 21.08.2019

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 239-001.08
- **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**



GHS07

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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Trade name: UltraSeal XT™ Hydro™

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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.*
- 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.*

- **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.*

- **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

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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.
- **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.

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- **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.

Upper: Not determined.

- **Vapour pressure:** Not determined.

- **Density at 20 °C:** 1.67 g/cm³

- **Relative density** Not determined.

- **Vapour density** Not determined.

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| | |
|--|--|
| · 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) | 0.00 % |
| · 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 |
| 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) |
| 79-41-4 Methacrylic Acid | | |
| Oral | LD50 | 1,250 mg/kg (mouse) |
| | | 1,060 mg/kg (rat) |
| | | 1,200 mg/kg (rabbit) |
| Dermal | LC50 Fish | 86 mg/l (Fish) |
| | LD50 | 1,000 mg/kg (Guinea pig) |
| Inhalative | LC50/4 h | 500 mg/kg (rabbit) |
| | | 7.1 mg/l (rat) |

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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
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.

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· **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**

| | |
|------|-------------|
| HPI3 | 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

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.

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Trade name: **UltraSeal XT™ Hydro™**

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

GB2