# SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

**UltraSeal XT® hydro™**

## SECTION 1: Identification of the substance/preparation and of the company/undertaking

### 1.1. Product identifier

- **Product code**: XI/71109, XJ/ 71110, XS/71111
- **Product name**: UltraSeal XT® hydro™
- **Product description**: Pit and fissure sealant

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Relevant identified uses**: Professional Dental Pit & Fissure Sealant

### 1.3. Details of the supplier of the safety data sheet

- **Manufacturer**: Ultradent Products, Inc.
  505 W. 10200 S.
  South Jordan, UT 84095
- **Distributor**: Ultradent Products GmbH
  Am Westhover Berg 30
  51149 Cologne Germany
  Email: infoDE@ultradent.com
  **Emergency Phone**: +49(0)2203-35-92-0

### 1.4. Emergency telephone number

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

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

**Classification according to Directive 1999/45/EC**

- The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

- **Danger symbols** : Xi
- **R phrases** : R43

**Classification according to Regulation (EC) No 1272/2008 [CLP]**

- **Health**: Skin Corrosion, Category 1A

### 2.2. Label elements

**Classification according to Directive 1999/45/EC**

- **Hazard pictogram(s)** : Xi

- **R&S statement(s)** : R43: May cause sensitization by skin contact.

**Classification according to Regulation (EC) No 1272/2008 [CLP]**

- **Hazard pictogram(s)** : 

- **Exclamation mark**
UltraSeal XT® hydro™

Signal Word : WARNING
Hazard statement(s) : H317: May cause an allergic skin reaction.
Precautionary statement(s)
Response : P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P333+P313: IF skin irritation or rash occurs: Get medical advice/attention.
Storage : P273: Avoid release to the environment.

2.3. Other hazards
Immediate concerns : No other adverse human effects.

SECTION 3: Composition / information on ingredients

3.1. Substances
Not Applicable
3.2. Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Directive 67/548/EEC</th>
<th>Classification according to Regulation (EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triethylene Glycol Dimethacrylate</td>
<td>109-16-0</td>
<td>203-652-6</td>
<td>&lt; 20</td>
<td>Xi; R43</td>
<td>H317</td>
</tr>
<tr>
<td>Methacrylic Acid</td>
<td>79-41-4</td>
<td>201-204-4</td>
<td>1</td>
<td>Xi; R36/37/38</td>
<td>Skin Corr.,Cat. 1A; Acute Tox. (O),Cat. 4; Acute Tox. (D),Cat. 4; H302; H312; H314</td>
</tr>
<tr>
<td>Sodium Monofluorophosphate</td>
<td>10163-15-2</td>
<td>233-433-0</td>
<td>&lt; 0.2</td>
<td>T; R22; R38</td>
<td>H315; H318; H301</td>
</tr>
</tbody>
</table>

For full text of H-statements and R-phrases: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures
Following eyes : No special measures required.
Following skin : Wash with soap and water. Get medical attention if irritation develops or persists.
UltraSeal XT® hydro™

**Following ingestion:** If swallowed in small quantity the product is harmless, otherwise consult a doctor.

**Following inhalation:** No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

### 4.2. Most important symptoms and effects, both acute and delayed

- **Eyes:** None expected for this product.
- **Skin:** May cause sensitization to skin.
- **Ingestion:** May be harmful if swallowed in large quantities.
- **Inhalation:** None expected for this product.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Notes to physician:** Not Applicable

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**SECTION 5: Fire fighting measures**

#### 5.1. Extinguishing media

**Extinguishing media:** Please see Fire Fighting Equipment under Section 5.3.

#### 5.2. Special hazards arising from the substance or mixture

- **Hazardous combustion products:** None known.
- **Explosion hazards:** Not Determined
- **Fire explosion:** Not Determined
- **Sensitive to static discharge:** Not Determined
- **Sensitivity to impact:** Not Determined

#### 5.3. Advice for firefighters

- **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).

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**SECTION 6: Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

**General procedures:** Refer to Section 8 for Personal Protective Equipment.

#### 6.2. Environmental precautions

- **Water spill:** Do not allow to enter sewers or drains that may lead to waterways.

#### 6.3. Methods and material for containment and cleaning up

- **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.
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6.4. Reference to other sections
Reference to other sections : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Handling : Use suitable protective equipment.
Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities
Shelf life : See product labeling

7.3. Specific end use(s)
Specific end use(s) : Professional Dental Pit & Fissure Sealant

SECTION 8: Exposure controls / personal protection

8.1. Control parameters
Control parameters : Not Determined

8.2. Exposure controls
Eye/face protection : Wear eye protection
Skin protection : Wear suitable protective clothing.
Respiratory protection : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Physical state : Liquid
Appearance : Tinted Liquid
Colour : Dependent upon color shade
Odour : Acrylic

9.2. Other information
Percent volatile : Not Determined

SECTION 10: Stability and reactivity

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

10.2. Chemical stability
Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions
Hazardous polymerization : None

10.4. Conditions to avoid
UltraSeal XT® hydro™

**Conditions to avoid**: Avoid light exposure.

**10.5. Incompatible materials**

Incompatible materials: Not Determined

**10.6. Hazardous decomposition products**

Hazardous decomposition products: None known.

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**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute**

Notes: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

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**SECTION 12: Ecological information**

**12.1. Toxicity**

Aquatic toxicity (acute)

- 96-hour LC$_{50}$: Not Determined
- 48-hour EC$_{50}$: Not Determined
- 96-hour EC$_{50}$: Not Determined

**12.2. Persistence and degradability**

Persistence and degradability: Not Determined

**12.3. Bioaccumulative potential**

Bioaccumulative potential: Not Determined

**12.4. Mobility in soil**

Mobility in soil: Not Determined

**12.5. Results of PBT and vPvB assessment**

Results of PBT and vPvB assessment: Not Determined

**12.6. Other adverse effects**

Environmental data: Not Available

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**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**


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**SECTION 14: Transport information**

**14.1. UN number**
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UN number : N/A

14.2. UN proper shipping name
UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)
Hazard classification : N/A

14.4. Packing group
Packing group : N/A

14.5. Environmental hazards
Marine pollutant #1 : N/A

14.6. Special precautions for user
ADR - road : Not Dangerous Goods
RID - rail : Not Dangerous Goods
IMDG - sea : Not Dangerous Goods
IATA - air : Not Dangerous Goods

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Transport in bulk : Not Dangerous Goods

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment
Chemical safety assessment : See Section 11

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text)
- R22: Harmful if swallowed.
- R36/37/38: Irritating to eyes, respiratory system and skin.
- R38: Irritating to skin.
- R43: May cause sensitization by skin contact.
- Acute Tox. (D), Cat. 4: Acute Toxicity (Dermal), Category 4
- Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
- Skin Corr., Cat. 1A: Skin Corrosion, Category 1A
- H301: Toxic if swallowed.
- H302: Harmful if swallowed.
- H312: Harmful in contact with skin.
- H314: Causes severe skin burns and eye damage.
- H315: Causes skin irritation.
- H317: May cause an allergic skin reaction.
- H318: Causes serious eye damage.

Prepared by : Anu Kattoju
Revision summary : This SDS replaces the 10/15/2014 SDS. Revised: Section 1: Section 2: Section 10: HAZARDOUS POLYMERIZATION,
UltraSeal XT® hydro™

STABLE, POSSIBILITY OF HAZARDOUS REACTIONS. **Section 11:** ACUTE (ORAL LD50 (rat), INHALATION LC50 (rat) ACUTE. **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1. **Section 15:** SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.

**General statements:** N/A = Not Applicable

**Manufacturer disclaimer:** FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(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.