

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010
Dental Use

ULTRADENT
PRODUCTS, INC.

Date Issued : 02/29/2012
SDS No : 239-001.5
Date Revised : 04/10/2015
Revision No : 4

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



Irritant

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

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Signal Word : WARNING

Hazard statement(s) : H317: May cause an allergic skin reaction.

Precautionary statement(s)

Prevention : P280: Wear protective gloves/protective clothing/eye protection/face protection.

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.

Disposal : P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

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

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

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.

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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

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).

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

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Conditions to avoid : Avoid light exposure.

10.5. Incompatible materials

Incompatible materials : Not Determined

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

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.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute)

96-hour LC₅₀ : Not Determined
48-hour EC₅₀ : Not Determined
96-hour EC₅₀ : 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

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

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.

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Revision summary : This SDS replaces the 10/15/2014 SDS. Revised: **Section 1:**
 . **Section 2:** . **Section 10:** HAZARDOUS POLYMERIZATION,

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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.