

SAFETY DATA SHEETS

This SDS packet was issued with item:

077640345

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).

077640303 077640337

SAFETY DATA SHEET



Date Issued : 9/25/2012
MSDS No : 25-001.7
Date-Revised : 11/6/2012
Revision No : 8

UltraSeal XT® Plus

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

PRODUCT NAME: UltraSeal XT® Plus

PRODUCT DESCRIPTION: Light cure pit and fissure sealant and flowable composite

PRODUCT CODE/ PART #: XA-73401, XB-13560, XR-56303, XT-10952, XU-71019

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.%
Diurethane Dimethacrylate	72869-86-4	276-957-5	Xi; R36/37/38	< 10
Bis GMA	1565-94-2	216-367-7	Xi; R36/37/38	< 20
2-dimethylaminoethyl Methacrylate	2867-47-2	220-688-8	T, Xi; R22, R34, R36/37/38, R43	< 1
Sodium Monofluorophosphate	10163-15-2	233-433-0	T; R22, R38	< 1
Titanium Dioxide	13463-67-7	236-675-5	R36/37/38, R22	< 1

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

3. HAZARDS IDENTIFICATION

HAZARD DESIGNATION

"Xi" - Irritant
R36/38: Irritating to eyes and skin.
"T" - Toxic
R22: Harmful if swallowed.

POTENTIAL HEALTH EFFECTS

EYES: Causes eye irritation.
SKIN: May cause skin irritation and sensitization.
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.

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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 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.

ENVIRONMENTAL PRECAUTIONS

WATER SPILL: Do not allow to enter sewers or drains that may lead to waterways.

7. HANDLING AND STORAGE

HANDLING: Use suitable protective equipment.

STORAGE: Refrigerate if not used on daily basis.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

PERSONAL PROTECTIVE EQUIPMENT

EYES AND FACE: Wear eye protection

SKIN: S36/37: Wear suitable protective clothing and gloves.

RESPIRATORY: Not needed for normal use.

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.

HAZARDOUS DECOMPOSITION PRODUCTS: Carbon Dioxide

11. TOXICOLOGICAL INFORMATION

EYE EFFECTS: Causes eye irritation.

SKIN EFFECTS: May cause skin irritation and sensitization.

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SENSITIZATION: Repeated or prolonged use, may cause irritation.

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL DATA: No data available.

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

ROAD AND RAIL (ADR/RID)

HAZARD CLASS: Not classified

LABEL: Not classified

AIR (ICAO/IATA)

PRIMARY HAZARD CLASS/DIVISION: Not classified

LABEL: Not classified

VESSEL (IMO/IMDG)

PRIMARY HAZARD CLASS/DIVISION: Not classified

LABEL: Not classified

15. REGULATORY INFORMATION

EUROPEAN COMMUNITY

EEC LABEL SYMBOL AND CLASSIFICATION



"Xi" - Irritant
R36/38: Irritating to eyes and skin.



"T" - Toxic
R22: Harmful if swallowed.

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

R22: Harmful if swallowed.

R34: Causes burns.

R43: May cause sensitization by skin contact.

R38: Irritating to skin.

PREPARED BY: Anu Kattoju

REVISION SUMMARY: This MSDS replaces the 7/19/2012 MSDS. Revised: **Section 1:** Date Issued, **PREPARED BY.** **Section 7:**

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STORAGE. **Section 15:** COMMENTS.

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 Regulation (EC) No. 453/2010
Dental Use

ULTRADENT
PRODUCTS, INC.

Date Issued : 09/25/2012
SDS No : 25-001.10
Date Revised : 07/07/2015
Revision No : 11

UltraSeal XT® Plus

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

1.1. Product identifier

Product code : XA/73401, XB/13560, XR/56303, XT/10952
Product name : UltraSeal XT® Plus
Product description : Light cure pit and fissure sealant and flowable composite

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

Relevant identified uses : Professional Dental Pit and 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 Westhoyer 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 : R36,R43

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

Health : Eye Irritation
Skin Irritation

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xi



Irritant

R&S statement(s) : R36: Irritating to eyes.
R43: May cause sensitization by skin contact.


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

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Hazard pictogram(s)	:	
		Exclamation mark
Signal Word	:	WARNING
Hazard statement(s)	:	H317: May cause an allergic skin reaction. H319: Causes serious eye irritation.
Precautionary statement(s)	:	
Prevention	:	P280: Wear protective gloves/protective clothing/eye protection/face protection.
Response	:	P305: IF IN EYES: P351: Rinse cautiously with water for several minutes. P337+P313: If eye irritation persists: Get medical advice/attention. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P332+P313: If skin irritation occurs: Get medical advice/attention.
Storage	:	P273: Avoid release to the environment.
Disposal	:	P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-10/11/2003)
2.3. Other hazards	:	
Immediate concerns	:	None

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]
Bis-GMA	1565-94-2	216-367-7	< 20	Xi; R36/37/38; R22	H315; H319; H317
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 20	Xi; R43	Not classified
Aluminum Oxide	1344-28-1	215-691-6	< 10	Xi; R36/37	Not classified
Sodium Monofluorophosphate	10163-15-2	233-433-0	< 1	T; R22; R38	Acute Tox. (O), Cat. 4; H302

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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** : Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.
- Following skin** : Wash with soap and water. Get medical attention if irritation develops or persists.
- 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** : Irritating to eyes.
- 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

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- 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.
- 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 and 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 and gloves.
- 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

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10.1. Reactivity

Reactivity : Stable

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

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 : No data available.

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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

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

Additional information : This product is not considered dangerous for transportation

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.
 R36/37: Irritating to eyes and respiratory system.
 R38: Irritating to skin.
 R43: May cause sensitization by skin contact.
 Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4

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H302: Harmful if swallowed.
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H319: Causes serious eye irritation.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 04/10/2015 SDS. Revised: **Section 1:** Date-
 Revised. **Section 15:** COMMENTS.

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.