

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 9/25/2012

SDS No : 25-001.8

Date Revised : 9/3/2014

Revision No : 9

**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 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**

**Danger symbols** : Xi  
**R phrases** : R36,R43

**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]**

**Hazard pictogram(s)** :



Exclamation mark

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**Signal Word** : WARNING  
**Hazard statement(s)** : H320: Causes eye irritation.  
 H317: May cause an allergic skin reaction.

**2.3. Other hazards**

**Immediate concerns** : Not Applicable

**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
Bis GMA	1565-94-2	216-367-7	< 20	Xi; R36/37/38;R22
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 20	Xi; R43
Diurethane Dimethacrylate	72869-86-4	276-957-5	< 10	Xi; R43
Aluminum Oxide	1344-28-1	215-691-6	< 10	Xi; R36/37
Sodium Monofluorophosphate	10163-15-2	233-433-0	< 1	T; R22; R38

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.

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**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 (CO<sub>2</sub>).

**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.

**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

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**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** : S36/37: 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**

**10.1. Reactivity**

**Stable** : Yes

**10.2. Chemical stability**

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

**10.3. Possibility of hazardous reactions**

**Possibility of hazardous reactions** : Polymerization occurs when exposed to visible lights, ultraviolet light or extreme heat.

**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**

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**Acute**

**Dermal LD<sub>50</sub>** : Not Determined  
**Oral LD<sub>50</sub>** : Not Determined  
**Inhalation LC<sub>50</sub>** : Not Determined  
**Sensitisation** : Repeated or prolonged use, may cause irritation.

**SECTION 12: Ecological information**

**12.1. Toxicity**

**Aquatic toxicity (acute)**

**96-hour LC<sub>50</sub>** : Not Determined  
**48-hour EC<sub>50</sub>** : Not Determined  
**96-hour EC<sub>50</sub>** : 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.

**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**

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Packing group : N/A

**14.5. Environmental hazards**

Marine pollutant #1 : Not Dangerous Goods

**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 : Not Determined

**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.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 11/6/2012 SDS. Revised: **Section 1:** GENERAL USE, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 3:** . **Section 4:** INGESTION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE ( INGESTION, INHALATION, SKIN ). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** GENERAL PROCEDURES, . **Section 7:** SHELF LIFE, STORAGE, . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . **Section 9:** PERCENT VOLATILE. **Section 10:** HAZARDOUS DECOMPOSITION PRODUCTS, INCOMPATIBLE MATERIALS, STABILITY, STABLE, POSSIBILITY OF HAZARDOUS REACTIONS. **Section 11:** ACUTE ( ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat) ). **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information. **Section 14:** AIR (ICAO/IATA) ( SPECIAL PROVISIONS ),

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ROAD AND RAIL (ADR/RID), ROAD AND RAIL (ADR/RID) ( PROPER SHIPPING NAME, UN NUMBER, PACKING GROUP ), VESSEL (IMO/IMDG) ( SPECIAL PROVISIONS ), ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS. **Section 15:** COMMENTS, RoHS, SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.

**General statements**

: NA = Not Applicable

**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.