

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

Printing date 11.12.2018

Revision: 10.10.2018

**1 Identification of the substance/mixture and of the company/undertaking**

- **Product identifier**
- **Trade name:** UltraSeal XT® plus
- **Article number:** XA/73401, XB/13560, XR/56303, XT/10952
- **Index number:** SDS: 25-001.15
- **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**



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  
2-Hydroxyethyl Methacrylate  
Amine Methacrylate

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- **Hazard statements**

H317 May cause an allergic skin reaction.

- **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	Triethylene Glycol Dimethacrylate	>10-≤25%
EINECS: 203-652-6	⚠ Skin Sens. 1, H317	
CAS: 72869-86-4	Diurethane Dimethacrylate	>2.5-≤10%
EINECS: 276-957-5	⚠ Skin Sens. 1, H317	
CAS: 1344-28-1	Aluminium Oxide	>2.5-≤10%
EINECS: 215-691-6	substance with a Community workplace exposure limit	
CAS: 868-77-9	2-Hydroxyethyl Methacrylate	≤2.5%
EINECS: 212-782-2	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
	Amine Methacrylate	≤2.5%
	⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 10163-15-2	Sodium Monofluorophosphate	0.1%
EINECS: 233-433-0	⚠ Acute Tox. 4, H302	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First aid measures

- **Description of first aid measures**

- **General information:** Immediately remove any clothing soiled by the product.

- **After inhalation:**

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 swallowed in large quantities seek medical attention.

- **Information for doctor:**

- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

## 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
Foam, dry chemical, carbon dioxide  
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:**  
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:**  
Avoid contact with eyes, skin, and clothing. Use suitable protective equipment.  
Ensure good ventilation/exhaustion at the workplace.
- **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:** See product labeling.
- **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:**

1344-28-1 Aluminium Oxide

WEL (Great Britain)	Long-term value: 10* 4** mg/m <sup>3</sup> *inhalable dust **respirable dust
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- **Additional information:** The lists valid during the making were used as basis.

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- **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..
- **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:** Not required.
- **Body protection:** Protective work clothing

## 9 Physical and chemical properties

### · Information on basic physical and chemical properties

#### · General Information

#### · Appearance:

<b>Form:</b>	Liquid
<b>Colour:</b>	Shade dependent
<b>Odour:</b>	Acrylic
<b>Odour threshold:</b>	Not determined.

· **pH-value:** Not applicable (non-aqueous)

#### · Change in condition

<b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	Undetermined.

· **Flash point:** >100 °C

· **Flammability (solid, gas):** Not determined.  
Not applicable.

· **Ignition temperature:** 445 °C

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

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· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure at 20 °C:</b>	0 hPa
· <b>Density at 20 °C:</b>	1.7-1.8 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Solvent content:</b>	
<b>VOC (EC)</b>	0.00 %
<b>Solids content:</b>	<60.0 %
· <b>Other information</b>	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:** Avoid light exposure
- **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.

· <b>LD/LC50 values relevant for classification:</b>		
<b>109-16-0 Triethylene Glycol Dimethacrylate</b>		
Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (mouse)
<b>72869-86-4 Diurethane Dimethacrylate</b>		
Oral	LD50	>5,000 mg/kg (rat)
<b>1344-28-1 Aluminium Oxide</b>		
Oral	LD50	>5,000 mg/kg (rat)
<b>868-77-9 2-Hydroxyethyl Methacrylate</b>		
Oral	LD50	3,275 mg/kg (mouse)

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Dermal	LC50 Fish	>5,000 mg/kg (rat)
	LD50	>100 mg/l (Fish)
	LC50(Daphnia magna)	>3,000 mg/kg (rabbit)
		24.1 mg/l (daphnia)
<b>Amine Methacrylate</b>		
Oral	LD50	1,550 mg/kg (rat)
	LC50 Fish	19 mg/l (Fish)
Dermal	LD50	2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	96 mg/l (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**

· <b>Aquatic toxicity:</b>	
<b>109-16-0 Triethylene Glycol Dimethacrylate</b>	
Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)
EC50	>100 mg/l (Algae) (Toxicity to algae)
<b>72869-86-4 Diurethane Dimethacrylate</b>	
Biodegradability	28 days (Aerobic) (Biodegradability testing)
EC50	>0.6 mg/l (Algae) (Toxicity to algae)
	>1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates)
<b>868-77-9 2-Hydroxyethyl Methacrylate</b>	
EC50	345 mg/l (Algae)
<b>Amine Methacrylate</b>	
EC50	42 mg/l (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.

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- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **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**

HP 13	Sensitising
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |   |                 |
|---|-----------------|
| · <b>UN-Number</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   | not regulated   |
| · <b>UN proper shipping name</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   | not regulated   |
| · <b>Transport hazard class(es)</b>   |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   |                 |
| · <b>Class</b>  | not regulated   |
| · <b>Packing group</b>  |                 |
| · <b>ADR, IMDG, IATA</b>  | not regulated   |
| · <b>Environmental hazards:</b>   | Not applicable. |
| · <b>Special precautions for user</b>                                       | Not applicable. |
| · <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>   | not regulated   |

### 15 Regulatory information

- **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.

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*H315 Causes skin irritation.**H317 May cause an allergic skin reaction.**H319 Causes serious eye irritation.**· 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**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1*

GB2