

## **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

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

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 09/25/2012  
SDS No : 25-001.11  
Date Revised : 04/20/2017  
Revision No : 12

## 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. Ultradent Drive (10200 South)  
South Jordan, UT 84095

##### EC Responsible Person

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 Regulation(EC) No 1272/2008 [CLP]

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

**Health** : Skin Sensitization, Category 1B

#### 2.2. Label elements

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

**Hazard pictogram(s)** :



Exclamation  
mark

**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.  
P261: Avoid breathing dust/fumes/gas/mist/vapours/spray.  
P272: Contaminated work clothing should not be allowed out of the workplace.

**Response** : P302+P352: IF ON SKIN: Wash with plenty of soap and water.

# SAFETY DATA SHEET

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



Date Issued : 09/25/2012  
SDS No : 25-001.11  
Date Revised : 04/20/2017  
Revision No : 12

## UltraSeal XT® Plus

**Storage** : P333+P313: If skin irritation or rash occurs: Get medical advice/attention.  
P363: Wash contaminated clothing before reuse.

**Disposal** : P273: Avoid release to the environment.  
P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-21/11/2003)

### 2.3. Other hazards

Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

## SECTION 3: Composition / information on ingredients

### 3.1. Substances

Not Applicable

### 3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Regulation(EC) No 1272/2008 [CLP]
Bis-GMA	1565-94-2	216-367-7	< 20	H315; H317; H319
TEGDMA	109-16-0	203-652-6	< 20	Skin Sens.,Cat. 1B; H317
Sodium Monofluorophosphate	10163-15-2	233-433-0	< 1	Acute Tox. (O),Cat. 4; H302

For full text of H-statements: 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 sensitization or irritation develops or persists. Wash contaminated clothing before reuse.

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

**Following inhalation** : Rest in the fresh air and seek medical advice if necessary.

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

**Eyes** : Irritating to eyes.

**Skin** : May cause skin irritation and sensitization.

**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** : NAP

## SECTION 5: Fire fighting measures

### 5.1. Extinguishing media

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



Date Issued : 09/25/2012  
 SDS No : 25-001.11  
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 Revision No : 12

**UltraSeal XT® Plus**

**Extinguishing media** : Foam, dry chemical, CO<sub>2</sub>

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

**Hazardous combustion products** : None known.

**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.

**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** : NAP

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

**General procedures** : Avoid contact with eyes, skin and clothing.

**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** : None Required

**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**

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



Date Issued : 09/25/2012  
SDS No : 25-001.11  
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**UltraSeal XT® Plus**

**Physical state** : Liquid  
**Appearance** : Medium viscosity  
**Colour** : White to tan  
**Odour** : Acrylic  
**pH** : NAP (non-aqueous)  
**Specific gravity** : 1.7 - 1.8

**9.2. Other information**

**Additional information** : No further relevant information available

**SECTION 10: Stability and reactivity**

**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**

**Dermal LD<sub>50</sub>** : > 2600 mg/kg Rabbit/Rat/Mouse

**Notes** : ~ 75% of the mixture consists of components of unknown toxicity (Dermal).

**Oral LD<sub>50</sub>** : > 4700 mg/kg Rat

**Notes** : 68% of the mixture consists of components of unknown toxicity (Oral).

**Inhalation LC<sub>50</sub>** : Not able to calculate ATE mix (inhalation) due to lack of data on the components.

**Germ cell mutagenicity** : The components in this product are not reported to produce mutagenic effects in humans.

**Carcinogenicity** : None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.

**Reproductive toxicity** : The components in this product are not reported to cause reproductive effects in humans.

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 Dental Use



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**UltraSeal XT® Plus**

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

**SECTION 12: Ecological information**

**12.1. Toxicity**

**Aquatic toxicity (acute)** : Do not empty into drains or the aquatic environment.

**12.2. Persistence and degradability**

**Persistence and degradability** : Not classified

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : Not classified

**12.4. Mobility in soil**

**Mobility in soil** : Not Available

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

**Results of PBT and vPvB assessment** : Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

**12.6. Other adverse effects**

**Environmental data** : No further relevant information 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** : NAP

**14.2. UN proper shipping name**

**UN proper shipping name** : Not Dangerous Goods

**14.3. Transport hazard class(es)**

**Hazard classification** : NAP

**14.4. Packing group**

**Packing group** : NAP

**14.5. Environmental hazards**

**Marine pollutant #1** : NAP

**14.6. Special precautions for user**

**ADR - road** : NAP

**RID - rail** : NAP

**IMDG - sea** : NAP

**IATA - air** : NAP

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



Date Issued : 09/25/2012  
SDS No : 25-001.11  
Date Revised : 04/20/2017  
Revision No : 12

**UltraSeal XT® Plus**

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Transport in bulk : NAP

**SECTION 15: Regulatory information**

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

**General information** : Substances of very high concern (SVHC) according to REACH, Article 57:  
Contains no SVHC substances.

**General comments** : Please refer to Medical Devices Directive 93/42/EEC.

**15.2. Chemical safety assessment**

**Chemical safety assessment** : See Section 11

**Additional information** : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.  
This product is not considered dangerous for transportation.

**SECTION 16: Other information**

**Relevant H-statements (number and full text)** : Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4  
Skin Sens., Cat. 1B: Skin Sensitization, Category 1B  
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 07/07/2015 SDS. Revised: **Section 1:** MSDS  
No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3.  
Other hazards. **Section 4:** INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE - SKIN SKIN. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** . **Section 7:** GENERAL PROCEDURES. **Section 8:** . **Section 9:** APPEARANCE, COLOR, COMMENTS, PERCENT VOLATILE, pH, SPECIFIC GRAVITY. **Section 11:** ACUTE ( DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat) ACUTE, GENERAL COMMENTS, CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.

**General statements** : NAP = Not Applicable

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**UltraSeal XT® Plus**

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NE = Not Established  
TLV = Threshold Limit Value  
PEL = Permittable exposure limits  
MAK = Maximum Workplace Concentration  
STEL = Short-term exposure limit  
STEV = Short-term exposure value  
TWA = Time Weighted Average  
PPE = Personal Protective Equipment

**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.



**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**



GHS07

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

(Contd. on page 2)

GB2

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 11.12.2018

Revision: 10.10.2018

Trade name: UltraSeal XT® plus

(Contd. of page 1)

- **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.

(Contd. on page 3)

GB2

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 11.12.2018

Revision: 10.10.2018

Trade name: UltraSeal XT® plus

(Contd. of page 2)

- **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.

(Contd. on page 4)

GB2

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 11.12.2018

Revision: 10.10.2018

Trade name: UltraSeal XT® plus

(Contd. of page 3)

- **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.

(Contd. on page 5)

GB2

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 11.12.2018

Revision: 10.10.2018

Trade name: UltraSeal XT® plus

(Contd. of page 4)

· <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)

(Contd. on page 6)

GB2

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 11.12.2018

Revision: 10.10.2018

Trade name: UltraSeal XT® plus

(Contd. of page 5)

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.

(Contd. on page 7)

GB2

## Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 11.12.2018

Revision: 10.10.2018

Trade name: UltraSeal XT® plus

(Contd. of page 6)

- **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.

(Contd. on page 8)

GB2

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(Contd. of page 7)

*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