

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

Printing date 13.03.2018

Revision: 19.12.2017

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

- **Product identifier**
- **Trade name:** Ultra Seal XT® Plus
- **Article number:** XA/73401, XB/13560, XR/56303, XT/10952
- **Index number:** SDS: 25-001.13
- **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 product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
Triethylene glycol dimethacrylate
DUDMA
2-hydroxyethyl methacrylate

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 13.03.2018

Revision: 19.12.2017

Trade name: Ultra Seal XT® Plus

(Contd. of page 1)

2-dimethylaminoethyl methacrylate

· **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	DUDMA	>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	
CAS: 2867-47-2	2-dimethylaminoethyl methacrylate	≤2.5%
EINECS: 220-688-8	⚠ Acute Tox. 2, H330; ⚠ 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**· **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)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 13.03.2018

Revision: 19.12.2017

Trade name: Ultra Seal 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:** Pick up mechanically.
- **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.
- **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:** None.
- **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	Long-term value: 10* 4** mg/m ³ *inhalable dust **respirable dust
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- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Immediately remove all soiled and contaminated clothing

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 13.03.2018

Revision: 19.12.2017

Trade name: Ultra Seal XT® Plus

(Contd. of page 3)

Wash hands before breaks and at the end of work.· **Respiratory protection:** Not required.· **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 the 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 break through 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:**

Form:	Liquid
Colour:	Shade dependent
Odour:	Acrylic
Odour threshold:	Not determined.

· **pH-value:** Not applicable (non-aqueous)· **Change in condition****Melting point/freezing point:** Undetermined.**Initial boiling point and boiling range:** Undetermined.· **Flash point:** >100 °C· **Flammability (solid, gas):** Not determined.· **Ignition temperature:** 445 °C· **Decomposition temperature:** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product does not present an explosion hazard.· **Explosion limits:****Lower:** Not determined.**Upper:** Not determined.· **Vapour pressure at 20 °C:** 0 hPa· **Density at 20 °C:** 1.7-1.8 g/cm³· **Relative density** Not determined.

(Contd. on page 5)

Safety data sheet

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Printing date 13.03.2018

Revision: 19.12.2017

Trade name: Ultra Seal XT® Plus

(Contd. of page 4)

· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
VOC (EC)	0.00 %
· Solids content:	<60.0 %
· Other information	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.

· LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Inhalative	LC50/4 h	310 mg/l (rat)
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109-16-0 Triethylene glycol dimethacrylate

Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (mouse)

72869-86-4 DUDMA

Oral	LD50	>5,000 mg/kg (rat)
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1344-28-1 aluminium oxide

Oral	LD50	>5,000 mg/kg (rat)
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868-77-9 2-hydroxyethyl methacrylate

Oral	LD50	3,275 mg/kg (mouse)
		>5,000 mg/kg (rat)
	LC50 Fish	>100 mg/l (Fish)
Dermal	LD50	>3,000 mg/kg (rabbit)
	LC50(Daphnia magna)	24.1 mg/l (daphnia)

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 13.03.2018

Revision: 19.12.2017

Trade name: Ultra Seal XT® Plus

(Contd. of page 5)

2867-47-2 2-dimethylaminoethyl methacrylate

Oral	LD50	1,550 mg/kg (rat)
	LC50 Fish	19 mg/l (Fish)
Dermal	LD50	2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	0.62 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**· **Aquatic toxicity:****109-16-0 Triethylene glycol dimethacrylate**

Aqua toxicity 32 mg/l (daphnia) (No Observed Effect Concentration)

EC50 >100 mg/l (Algae) (Toxicity to algae)

72869-86-4 DUDMA

EC50 >0.6 mg/l (Algae) (Toxicity to algae)

>1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates)

2867-47-2 2-dimethylaminoethyl methacrylate

EC50 825 mg/kg (daphnia)

- **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.
- **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.

(Contd. on page 7)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 13.03.2018

Revision: 19.12.2017

Trade name: Ultra Seal XT® Plus

(Contd. of page 6)

· **European waste catalogue**

HP 13 Sensitising

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN-Number**· **ADR, ADN, IMDG, IATA** not regulated· **UN proper shipping name**· **ADR, ADN, IMDG, IATA** not regulated· **Transport hazard class(es)**· **ADR, ADN, IMDG, IATA**· **Class** not regulated· **Packing group**· **ADR, IMDG, IATA** not regulated· **Environmental hazards:**

Not applicable.

· **Special precautions for user**

Not applicable.

· **Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

· **UN "Model Regulation":**

not regulated

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**· **Directive 2012/18/EU**· **Named dangerous substances - ANNEX I** None of the ingredients is listed.· **Chemical safety assessment:**

Mixtures are components of a medical device which has undergone biocompatibility evaluation and/or testing.

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.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H330 Fatal if inhaled.

· **Department issuing SDS:** Regulatory Affairs· **Contact:** Customer Service

(Contd. on page 8)

Safety data sheet
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Revision: 19.12.2017

Trade name: Ultra Seal XT® Plus

(Contd. of page 7)

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

Acute Tox. 2: Acute toxicity – Category 2

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

GB