

Safety data sheet
according to UK REACH

Printing date 11.11.2024

Version number 1

Revision: 11.11.2024

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

- **Product identifier**
- **Trade name:** *UltraSeal XT™ Plus*
- **Article number:** *SDS 25-001.17R01, 13560, 56303, 10952, 73401*
- **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
- **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** *Void*
- **Hazard pictograms** *GHS07*
- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
Triethylene Glycol Dimethacrylate
Diurethane Dimethacrylate
Irgacure 819
2-Hydroxyethyl Methacrylate
Trade Secret
- **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 carefully and follow all instructions.
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.

(Contd. on page 2)

Safety data sheet according to UK REACH

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Version number 1

Revision: 11.11.2024

Trade name: UltraSeal XT™ Plus

(Contd. of page 1)

P321 Specific treatment (see on this label).

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition/information on ingredients

- **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; Aquatic Chronic 3, H412	
CAS: 868-77-9	2-Hydroxyethyl Methacrylate	≥0.1-<1%
EINECS: 212-782-2	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
	Trade Secret	≥0.1-<1%
	⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
	Irgacure 819	<0.1%
	⚠ Skin Sens. 1A, H317; Aquatic Chronic 4, H413	

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

(Contd. on page 3)

Safety data sheet

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Printing date 11.11.2024

Version number 1

Revision: 11.11.2024

Trade name: UltraSeal XT™ Plus

(Contd. of page 2)

- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to section 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

- **Precautions for safe handling:**
Avoid contact with eyes, skin, and clothing. Use suitable protective equipment.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **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

- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as 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.
- **Hand protection**



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.

(Contd. on page 4)

Safety data sheet

according to UK REACH

Printing date 11.11.2024

Version number 1

Revision: 11.11.2024

Trade name: UltraSeal XT™ Plus

(Contd. of page 3)

- **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/face protection** Goggles recommended during refilling
- **Body protection:** Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

- | | |
|---|------------------------------|
| · Physical state | Fluid |
| · Colour: | Shade dependent |
| · Odour: | Acrylic |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | Undetermined. |
| · Boiling point or initial boiling point and boiling range | Undetermined. |
| · Flammability | Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | >100 °C |
| · Decomposition temperature: | Not determined. |
| · pH | Not applicable (non-aqueous) |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · Dynamic: | Not determined. |
| · Solubility | |
| · water: | Partly miscible. |
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Vapour pressure at 20 °C: | 0 hPa |
| · Density and/or relative density | |
| · Density at 20 °C: | 1.7-1.8 g/cm ³ |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |

· Other information

- | | |
|--|---|
| · Appearance: | |
| · Form: | Medium-High Viscosity Liquid |
| · Important information on protection of health and environment, and on safety. | |
| · Ignition temperature: | Product is not selfigniting. |
| · Explosive properties: | Product does not present an explosion hazard. |
| · Change in condition | |
| · Evaporation rate | Not determined. |

· Information with regard to physical hazard classes

- | | |
|-------------------------------|------|
| · Explosives | Void |
| · Flammable gases | Void |
| · Aerosols | Void |
| · Oxidising gases | Void |
| · Gases under pressure | Void |
| · Flammable liquids | Void |
| · Flammable solids | Void |

(Contd. on page 5)

Safety data sheet

according to UK REACH

Printing date 11.11.2024

Version number 1

Revision: 11.11.2024

Trade name: UltraSeal XT™ Plus

(Contd. of page 4)

· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

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 Diurethane Dimethacrylate

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)

Trade Secret

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)

Irgacure 819

Oral	LD50	>2,000 mg/kg (rat)
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(Contd. on page 6)

Safety data sheet

according to UK REACH

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Version number 1

Revision: 11.11.2024

Trade name: UltraSeal XT™ Plus

(Contd. of page 5)

Dermal	LC50 Fish	>0.09 mg/l (Fish) (Toxicity to fish)
	LD50	>2,000 mg/kg (rat)
<ul style="list-style-type: none"> · Respiratory or skin sensitisation May cause an allergic skin reaction. · Information on other hazards 		
<ul style="list-style-type: none"> · Endocrine disrupting properties 		
None of the ingredients is listed.		

12 Ecological information

- **Toxicity**

<ul style="list-style-type: none"> · Aquatic toxicity: 	
109-16-0 Triethylene Glycol Dimethacrylate	
EC50	>100 mg/kg (Algae)
Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)
72869-86-4 Diurethane Dimethacrylate	
EC50	>0.6 mg/kg (Algae)
Biodegradability	28 days (Aerobic) (Biodegradability testing)
868-77-9 2-Hydroxyethyl Methacrylate	
EC50	345 mg/kg (Algae)
Trade Secret	
EC50	42 mg/kg (Algae)
Irgacure 819	
EC50 (static)	>1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
Aqua toxicity	≥0.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)
Toxicity to Aquatic Plants (static)	>0.26 mg/l (Plant) (Toxicity to algae)

- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.
- **Other adverse effects**
- **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.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
Dispose of contents/container in accordance with international, federal, state, and local regulations.

(Contd. on page 7)

GB

Safety data sheet according to UK REACH

Printing date 11.11.2024

Version number 1

Revision: 11.11.2024

Trade name: UltraSeal XT™ Plus

(Contd. of page 6)

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

14 Transport information

· UN number or ID 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
· Maritime transport in bulk according to IMO instruments	Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture
· NIOSH-Ca (National Institute for Occupational Safety and Health) None of the ingredients is listed.
· Poisons Act
· Regulated explosives precursors None of the ingredients is listed.
· Regulated poisons None of the ingredients is listed.
· Reportable explosives precursors None of the ingredients is listed.
· Reportable poisons None of the ingredients is listed.
· Directive 2012/18/EU
· Named dangerous substances - ANNEX I None of the ingredients is listed.
· Chemical safety assessment: Device is biocompatible when used as directed by dental professionals per ISO 10993-1

GB

(Contd. on page 8)

Safety data sheet according to UK REACH

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Version number 1

Revision: 11.11.2024

Trade name: UltraSeal XT™ Plus

(Contd. of page 7)

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 from Section 3**

- 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.
- H412 Harmful to aquatic life with long lasting effects.
- H413 May cause long lasting harmful effects to aquatic life.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

- ADR: Accord relatif au transport international 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)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- NIOSH: National Institute for Occupational Safety
- ATE: Acute toxicity estimate values
- 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
- Skin Sens. 1A: Skin sensitisation – Category 1A
- Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
- Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

· *** Data compared to the previous version altered.**