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@utradent.com
  - 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
- 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
Trade name: UltraSeal XT® plus

- **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:**

<table>
<thead>
<tr>
<th>CAS:</th>
<th>Chemical Name</th>
<th>Skin Sens.</th>
<th>Acute Tox. 4</th>
<th>Acute Tox. 4</th>
<th>Acute Tox. 4</th>
<th>Acute Tox. 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>109-16-0</td>
<td>Triethylene Glycol Dimethacrylate</td>
<td>≥10% ≤25%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>72869-86-4</td>
<td>Diurethane Dimethacrylate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1344-28-1</td>
<td>Aluminium Oxide</td>
<td>≥2.5% ≤10%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>868-77-9</td>
<td>2-Hydroxyethyl Methacrylate</td>
<td>≤2.5%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10163-15-2</td>
<td>Sodium Monofluorophosphate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **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.
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/m³
      *inhalable dust **respirable dust
- 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.
  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:
  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.
  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.
Trade name: UltraSeal XT® plus

- 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.
  - 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:

<table>
<thead>
<tr>
<th>109-16-0 Triethylene Glycol Dimethacrylate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Dermal</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>72869-86-4 Diurethane Dimethacrylate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
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<tr>
<td>Oral</td>
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</table>

<table>
<thead>
<tr>
<th>868-77-9 2-Hydroxyethyl Methacrylate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
</tr>
</tbody>
</table>
Trade name: UltraSeal XT® plus

<table>
<thead>
<tr>
<th>Dermal</th>
<th>LC50 Fish</th>
<th>&gt;5,000 mg/kg (rat)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LD50</td>
<td>&gt;100 mg/l (Fish)</td>
</tr>
<tr>
<td></td>
<td>LC50(Daphnia magna)</td>
<td>24.1 mg/l (daphnia)</td>
</tr>
</tbody>
</table>

Amine Methacrylate

<table>
<thead>
<tr>
<th>Oral</th>
<th>LD50</th>
<th>1,550 mg/kg (rat)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LC50 Fish</td>
<td>19 mg/l (Fish)</td>
</tr>
<tr>
<td>Dermal</td>
<td>LD50</td>
<td>2,000 mg/kg (rabbit)</td>
</tr>
<tr>
<td>Inhalative</td>
<td>LC50/4 h</td>
<td>96 mg/l (rat)</td>
</tr>
</tbody>
</table>

- 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 (cancerogenity, 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**
  - Biodegradability: 28 days (Aerobic) (Biodegradability testing)
  - Aqua toxicity: 32 mg/l (daphnia) (No Observed Effect Concentration)
  - EC50 >100 mg/l (Algae) (Toxicity to algae)

  **72869-86-4 Diurethane Dimethacrylate**
  - Biodegradability: 28 days (Aerobic) (Biodegradability testing)
  - EC50 >0.6 mg/l (Algae) (Toxicity to algae)
  - >1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates)

  **868-77-9 2-Hydroxyethyl Methacrylate**
  - EC50 >345 mg/l (Algae)

  Amine Methacrylate
  - 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.
48.0

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

· 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

· 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.
Trade name: UltraSeal XT® plus

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