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

· Product identifier
  · Trade name: Ultrapro™ Tx Prophy Paste
  · Article number: 8309, 8310, 8311, 8312, 8313, 8314, 8315, 8320, 8321, 8322, 8323, 8324, 8326, 8327
  · Index number: SDS 213-001.06
  · Relevant identified uses of the substance or mixture and uses advised against: Professional Dental Prophy Paste
  · Application of the substance / the mixture: Professional Dental Prophy Paste

· 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

  Acute Tox. 4 H302 Harmful if swallowed.

· 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:
  Phosphoric Acid
  Sodium Fluoride
  Sodium Silicate Solution

· Hazard statements
  H302 Harmful if swallowed.
3 Composition/information on ingredients

· Chemical characterisation: Mixtures
· Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

<table>
<thead>
<tr>
<th>CAS: 7757-79-1</th>
<th>Potassium Nitrate</th>
<th>≤5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 231-818-8</td>
<td>Ox. Sol. 2, H272; Skin Irrit. 2, H315; STOT SE 3, H335-H336</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 7664-38-2</th>
<th>Phosphoric Acid</th>
<th>≤5%</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>CAS: 1344-09-8</th>
<th>Sodium Silicate Solution</th>
<th>3%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 215-687-4</td>
<td>Acute Tox. 3, H331; Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 7681-49-4</th>
<th>Sodium Fluoride</th>
<th>2.7%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 231-667-8</td>
<td>Acute Tox. 3, H301; Acute Tox. 2, H310; Skin Irrit. 2, H315; Eye Irrit. 2, H319</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:
  Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
· After inhalation: Supply fresh air; consult doctor in case of complaints.
· After skin contact: After contact with skin, wash immediately with: Water and soap.
· 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
  For symptoms and effects caused by the contained substances, see Section 11.
· Indication of any immediate medical attention and special treatment needed
  No further relevant information available.
5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
  - Foam
  - Water
  - 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:**
  - Wear self-contained respiratory protective device.
  - Wear fully protective suit.
- **Additional information** Cool endangered receptacles with water spray.

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.
- **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:** Keep away from heat and direct sunlight.
- **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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** See product labelling.
- **Specific end use(s) Professional Dental Prophy Paste**

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:**
  
<table>
<thead>
<tr>
<th>7664-38-2 Phosphoric Acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEL (Great Britain)</td>
</tr>
<tr>
<td>Short-term value: 2 mg/m³</td>
</tr>
<tr>
<td>Long-term value: 1 mg/m³</td>
</tr>
</tbody>
</table>

(Contd. on page 4)
Trade name: Ultrapro™ Tx Prophy Paste

7681-49-4 Sodium Fluoride
WEL (Great Britain) Long-term value: 2.5 mg/m³ as F

- Additional information: The lists valid during the making were used as basis.

- Exposure controls
- Personal protective equipment:
- General protective and hygienic measures:
  Keep away from foodstuffs, beverages and feed.
  Wash hands before breaks and at the end of work.
- Respiratory protection: Not required.
- Protection of hands:
  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: Paste
    - Colour: Color Dependent
    - Odour: Flavor Dependent
    - Odour threshold: Not determined.
  - pH-value: Not applicable.
- Change in condition
  - Melting point/freezing point: Undetermined.
  - Initial boiling point and boiling range: Not determined
- Flash point: Not determined
- Flammability (solid, gas): Not determined.
  - Not applicable.
- 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.
### 10 Stability and reactivity

- **Reactivity**: No further relevant information available.
- **Chemical stability**
  - **Thermal decomposition / conditions to be avoided**: No decomposition if used and stored according to specifications.
  - **Possibility of hazardous reactions**: Reacts with oxidising agents. Reacts with acids.
- **Conditions to avoid**: No further relevant information available.
- **Incompatible materials**: No further relevant information available.
- **Hazardous decomposition products**: No dangerous decomposition products known.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**
  - Harmful if swallowed.
- **LD/LC50 values relevant for classification**:
  - **ATE (Acute Toxicity Estimates)**
    - Oral: LD50 ≥1,652 mg/kg
    - Dermal: LD50 6,481 mg/kg
    - Inhalative: LC50/4 h ≥7.52 mg/l

#### 7757-79-1 Potassium Nitrate

- **Oral**
  - LD50 3,015 mg/kg (rat)
  - LC50 Fish 1,901 mg/kg (rabbit)
- **Dermal**
  - LC50 Fish 1,378 mg/l (Fish)
  - LD50 >5,000 mg/kg (rat)
## Trade name: Ultrapro™ Tx Prophy Paste

### 12 Ecological information

#### Toxicity

- **Aquatic toxicity:**
  
  | 1344-09-8 Sodium Silicate Solution |  
  | EC50 | 1,700 mg/l (daphnia) |  
  
  | 7681-49-4 Sodium Fluoride |  
  | EC50 | 272 mg/kg (Algae) | 98 mg/kg (daphnia) |  
  | Algae Toxicity (static) | 7 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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
Trade name: Ultrapro™ Tx Prophy Paste

· 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 6 Acute Toxicity
  HP 8 Corrosive

· Uncleaned packaging:
  · Recommendation: Disposal must be made according to official regulations.
  · Recommended cleansing agents: Water, if necessary together with cleansing agents.

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 not regulated
    · Class

· 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
  H272 May intensify fire; oxidiser.
  H290 May be corrosive to metals.
Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 18.04.2019
Revision: 12.12.2018

Trade name: Ultrapro™ Tx Prophy Paste

H301 Toxic if swallowed.
H302 Harmful if swallowed.
H310 Fatal in contact with skin.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H330 Fatal if inhaled.
H331 Toxic if inhaled.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.

· 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
  Ox. Sol. 2: Oxidizing solids – Category 2
  Met. Corr. 1: Corrosive to metals – Category 1
  Acute Tox. 4: Acute toxicity – Category 4
  Acute Tox. 2: Acute toxicity – Category 2
  Acute Tox. 1: Acute toxicity – Category 1
  Acute Tox. 3: Acute toxicity – Category 3
  Skin Corr. 1B: Skin corrosion/irritation – Category 1B
  Skin Irrit. 2: Skin corrosion/irritation – Category 2
  Eye Dam. 1: Serious eye damage/eye irritation – Category 1
  Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  STOT SE 3: Specific target organ toxicity (single exposure) – Category 3