

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/26/2012

SDS No : 339-001.2

Date Revised : 06/23/2015

Revision No : 1

**Ultrapro® Tx Prophy Paste Pure****SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

**Product code** : 8325  
**Product name** : Ultrapro® Tx Prophy Paste Pure  
**Product description** : Dental Prophylaxis Paste

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

**Relevant identified uses** : Professional Dental Prophy Paste

**1.3. Details of the supplier of the safety data sheet****Manufacturer**

Ultradent Products, Inc.  
 505 W. 10200 S.  
 South Jordan, UT 84095

**Distributor**

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 Directive 1999/45/EC**

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

**Danger symbols** : Xi

**R phrases** : R36/38

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

**Health** : Eye Irritation  
 Skin Irritation

**2.2. Label elements****Classification according to Directive 1999/45/EC**

**Hazard pictogram(s)** : Xi



Irritant

**R&S statement(s)** : R36/38: Irritating to eyes and skin.

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

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**ULTRADENT**  
 PRODUCTS, INC.

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**Hazard pictogram(s)**



Exclamation  
 mark

**Signal Word**

: DANGER

**Hazard statement(s)**

: H315: Causes skin irritation.  
 H319: Causes serious eye irritation.

**Precautionary statement(s)**

**Prevention**

: P280: Wear protective gloves/protective clothing/eye protection/face protection.

**Response**

: P305: IF IN EYES:  
 P351: Rinse cautiously with water for several minutes.  
 P337+P313: If eye irritation persists: Get medical advice/attention.  
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.  
 P332+P313: If skin irritation occurs: Get medical advice/attention.

**Storage**

: P273: Avoid release to the environment.

**Disposal**

: P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-20/11/2003)

**2.3. Other hazards**

**Immediate concerns**

: None

**SECTION 3: Composition / information on ingredients**

**3.1. Substances**

Not Applicable

**3.2. Mixtures**

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Sodium Silicate	1344-09-8	215-687-4	< 15	Xi; R22; R36/37/38	Acute Tox. (O), Cat. 4; Skin Irr., Cat. 2; EYE DMG., Cat. 1; H302; H315; H318
Phosphoric Acid	7664-38-2	231-633-2	≤ 5	C; R34	Skin Corr., Cat. 1B; H314

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For full text of H-statements and R-phrases: see SECTION 16.

**SECTION 4: First aid measures**

**4.1. Description of first aid measures**

- Following eyes** : Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes.
- Following skin** : Wash with soap and water. Get medical attention if irritation develops or persists.
- Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.
- Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

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

- Eyes** : May cause eye irritation.
- Skin** : May cause slight irritation.
- 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** : Not Applicable

**SECTION 5: Fire fighting measures**

**5.1. Extinguishing media**

- Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.

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

- Hazardous combustion products** : Not Determined
- Explosion hazards** : Not Determined
- Fire explosion** : Not Determined
- Sensitive to static discharge** : Not Determined
- Sensitivity to impact** : Not Determined

**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.
- Fire fighting equipment** : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO<sub>2</sub>)

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

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**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** : Wipe up with cloth, soap and water.

**Large spill** : After removal, flush contaminated area thoroughly with water.

**6.4. Reference to other sections**

**Reference to other sections** : Not Applicable

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

**Handling** : Avoid contact with eyes, skin, and clothing.

**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 Prophy Paste

**SECTION 8: Exposure controls / personal protection**

**8.1. Control parameters**

**Control parameters** : Not Determined

**8.2. Exposure controls**

**Eye/face protection** : Wear eye protection

**Skin protection** : Wear suitable 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**

**Physical state** : Paste

**Colour** : Gray

**Odour** : No characteristic odor

**9.2. Other information**

**Percent volatile** : Not Volatile

**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

**Reactivity** : Stable

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**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** : Heat

**10.5. Incompatible materials**

**Incompatible materials** : Strong oxidizing agents. Strong acids.

**10.6. Hazardous decomposition products**

**Hazardous decomposition products** : None known.

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute**

**Notes** : 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 allow to enter sewers or drains that may lead to waterways.

**96-hour LC<sub>50</sub>** : Not Determined

**48-hour EC<sub>50</sub>** : Not Determined

**96-hour EC<sub>50</sub>** : Not Determined

**12.2. Persistence and degradability**

**Persistence and degradability** : Not Determined

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : None

**12.4. Mobility in soil**

**Mobility in soil** : Not Determined

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

**12.6. Other adverse effects**

**Environmental data** : Biodegradable

**Additional information** : Negligible ecotoxicity.

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

**Disposal method** : Dispose of in compliance with governmental regulation.(EC

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1975L0442-20/11/2003)

**SECTION 14: Transport information**

**14.1. UN number**

**UN number** : N/A

**14.2. UN proper shipping name**

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

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

**Primary hazard class/division** : N/A

**Hazard classification** : N/A

**14.4. Packing group**

**Packing group** : N/A

**14.5. Environmental hazards**

**Marine pollutant #1** : N/A

**14.6. Special precautions for user**

**ADR - road** : Not Dangerous Goods

**RID - rail** : Not Dangerous Goods

**IMDG - sea** : Not Dangerous Goods

**IATA - air** : Not Dangerous Goods

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

**Transport in bulk** : Not Dangerous Goods

**SECTION 15: Regulatory information**

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

**RoHS** : Please refer to Medical Devices Directive 93/42/EEC

**15.2. Chemical safety assessment**

**Chemical safety assessment** : See Section 11

**Additional information** : This product is not considered dangerous for transportation

**SECTION 16: Other information**

**Relevant R-phrases and/or H-statements (number and full text)** : R22: Harmful if swallowed.  
 R34: Causes burns.  
 R36/37/38: Irritating to eyes, respiratory system and skin.  
 Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4  
 EYE DMG., Cat. 1: Eye Damage, Category 1  
 Skin Corr., Cat. 1B: Skin Corrosion, Category 1B  
 Skin Irr., Cat. 2: Skin Irritation, Category 2  
 H302: Harmful if swallowed.  
 H314: Causes severe skin burns and eye damage.

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H315: Causes skin irritation.

H318: Causes serious eye damage.

**Prepared by**

: Anu Kattoju

**Revision summary**

: This SDS replaces the 09/26/2012 SDS. Revised: **Section 1:** GENERAL USE, PREPARED BY, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 3:** Wt. %. **Section 4:** NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE ( INGESTION, INHALATION, SKIN ). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** GENERAL PROCEDURES, . **Section 7:** HANDLING, SHELF LIFE, STORAGE, . **Section 8:** ENGINEERING CONTROLS, PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . **Section 9:** PERCENT VOLATILE. **Section 10:** HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABILITY, STABLE. **Section 11:** ACUTE. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ). **Section 14:** ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information. **Section 15:** COMMENTS, RoHS, SECTION 15: Regulatory information. **Section 16:** Revision Summary, GENERAL STATEMENTS.

**General statements**

: N/A= Not Applicable

**Additional SDS information**

: Revision #:1

**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.