

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010  
Dental Use

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 08/28/2012  
SDS No : 10-001.12  
Date Revised : 09/23/2016  
Revision No : 14

## UltraCal® XS

### SECTION 1 : Identification of the substance/preparation and of the company/undertaking

#### 1.1. Product identifier

Product code : CX/41711  
Product name : UltraCal® XS  
Product description : Calcium Hydroxide Paste

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

Relevant identified uses : Professional Dental Cavity Liner

#### 1.3. Details of the supplier of the safety data sheet

##### Manufacturer

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

##### 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

#### 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 : C

R phrases : R34

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

Health : Acute Toxicity (Oral), Category 4  
Skin Irritation, Category 2  
Eye Damage, Category 1

#### 2.2. Label elements

##### Classification according to Directive 1999/45/EC

Hazard pictogram(s) : C



Corrosive

R& statement(s) : R34: Causes burns.

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

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**Hazard pictogram(s)**

**Signal Word**

: DANGER

**Hazard statement(s)**

: H318: Causes serious eye damage.  
H315: Causes skin irritation.

**Precautionary statement(s)**
**Prevention**

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

**Response**

: P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P313: Get medical advice/attention.  
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  
P315: Get immediate medical advice/attention.  
P363: Wash contaminated clothing before reuse.  
P301: IF SWALLOWED:  
P330: Rinse mouth.  
P310: Immediately call a POISON CENTER or doctor/physician.  
P331: Do NOT induce vomiting.

**Storage**

: P273: Avoid release to the environment.

**Disposal**

: P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003

### 2.3. Other hazards

Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

## 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]         |
|-------------------|-----------|------------|-------|--|--|
| Calcium Hydroxide | 1305-62-0 | 215-137-3  | ≤ 35  | C; R34   | Skin Irr., Cat. 2; EYE DMG., Cat. 1; STOT SE, Cat. 3; H315; H318; H335 |
| Barium Sulfate    | 7727-43-7 | 231-784-4  | ≤ 20  | Xi; R 36/38                                      | Not classified   |

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

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|                             |  |
|-----------------------------|--|
| <b>Following eyes</b>       | : Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Have eyes examined and tested by medical personnel. |
| <b>Following skin</b>       | : Immediately flush skin with plenty of water. Remove clothing. Get medical attention immediately. Wash clothing separately before reuse.  |
| <b>Following ingestion</b>  | : If swallowed, rinse mouth with water, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center if you feel unwell.                            |
| <b>Following inhalation</b> | : No specific treatment is necessary since this material is not likely to be hazardous by inhalation.  |

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

|                   |  |
|-------------------|--|
| <b>Eyes</b>       | : Causes severe eye damage.  |
| <b>Skin</b>       | : Irritating to skin.  |
| <b>Ingestion</b>  | : Ingestion of this material can cause mouth, throat, esophageal, and gastrointestinal tract irritation. |
| <b>Inhalation</b> | : None expected for this product.  |

**4.3. Indication of any immediate medical attention and special treatment needed**

|                           |             |
|---------------------------|-------------|
| <b>Notes to physician</b> | : Corrosive |
|---------------------------|-------------|

**SECTION 5: Fire fighting measures**

**5.1. Extinguishing media**

|                            |   |
|----------------------------|---|
| <b>Extinguishing media</b> | : The material is non-combustible. If involved in fire water may be used to cool the surrounding areas. |
|----------------------------|---|

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

|                                      |               |
|--------------------------------------|---------------|
| <b>Hazardous combustion products</b> | : None known. |
|--------------------------------------|---------------|

**5.3. Advice for firefighters**

|                                 |   |
|---------------------------------|---|
| <b>Fire fighting procedures</b> | : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire. |
|---------------------------------|---|

**SECTION 6: Accidental release measures**

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

|                           |   |
|---------------------------|---|
| <b>General procedures</b> | : Refer to Section 8 for Personal Protective Equipment. |
|---------------------------|---|

**6.2. Environmental precautions**

|                    |  |
|--------------------|--|
| <b>Water spill</b> | : Do not allow to enter sewers or drains that may lead to waterways. |
|--------------------|--|

**6.3. Methods and material for containment and cleaning up**

|                    |   |
|--------------------|---|
| <b>Small Spill</b> | : Clean up spills immediately, observing precautions in Protective Equipment section. |
| <b>Large Spill</b> | : Collect in tightly closed containers.   |

**6.4. Reference to other sections**

|                                    |                  |
|------------------------------------|------------------|
| <b>Reference to other sections</b> | : Not Applicable |
|------------------------------------|------------------|

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**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

**Handling** : Use suitable protective equipment.  
**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 Cavity Liner

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

**8.1. Control parameters**

**Control parameters** : Calcium Hydroxide CAS: 1305-62-0

| Control Parameters     | Exposure Limits          |
|------------------------|--------------------------|
| OSHA Maritime Industry | 15 mg/m <sup>3</sup> TWA |
| OSHA General Industry  | 15 mg/m <sup>3</sup> TWA |
| NIOSH REL              | 5mg/m <sup>3</sup> TWA   |
| ACGIH TLV              | 5mg/m <sup>3</sup> TWA   |
| AIHA WHEEL             | None                     |

Calcium Hydroxide CAS: 1305-62-0  
International Control Parameters  
Canada

|                  |                             |
|------------------|-----------------------------|
| Alberta          | = 5mg/m <sup>3</sup> TWA    |
| British Columbia | = 5mg/m <sup>3</sup> TWA    |
| Ontario          | = 5mg/m <sup>3</sup> TWA    |
| Quebec           | = 5 mg/m <sup>3</sup> TWAEV |

Calcium Hydroxide CAS: 1305-62-0  
Australia: 5mg/m<sup>3</sup> TWA  
Mexico + 5 mg/m<sup>3</sup> TWA

Barium Sulfate CAS: 7727-43-7

| Control Parameters | Exposure Limits  |
|--------------------|--|
| ACGIH TLV          | 10 mg/m <sup>3</sup> TWA; The value is for particulate matter containing no asbestos and < 1% crystalline Silica |
| NIOSH REL          | 10 mg/m <sup>3</sup> TWA   |

**8.2. Exposure controls**

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**Eye/face protection** : Wear safety glasses with side shields (or goggles) and a face shield.  
**Skin protection** : Wear suitable protective clothing and 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** : High Viscosity Paste  
**Colour** : White to Off-White  
**Odour** : Odorless or no characteristic odor  
**pH** : 12.0 to 13.0  
**Specific gravity** : 1.4 to 1.5

**9.2. Other information**

**Percent volatile** : Not Volatile

**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

**Reactivity** : Stable

**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** : Acidic conditions.

**10.5. Incompatible materials**

**Incompatible materials** : Strong acids, metals

**10.6. Hazardous decomposition products**

**Hazardous decomposition products** : None known.

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute**

**Dermal LD<sub>50</sub>** : > 18000 mg/kg (Rabbit)  
**Notes** : ~55% of the mixture consists of components of unknown toxicity (dermal).  
**Oral LD<sub>50</sub>** : > 1200 mg/kg (mouse/rat/rabbit)  
**Notes** : There are no components of unknown toxicity (Oral).  
**Inhalation LC<sub>50</sub>** : Not able to calculate ATE mix (inhalation) due to lack of data on the components.  
**Other information** : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

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**SECTION 12: Ecological information**

**12.1. Toxicity**

**Aquatic toxicity (acute)** : Do not allow to enter sewers or drains that may lead to waterways.

**12.2. Persistence and degradability**

**Persistence and degradability** : Not classified

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : Not classified

**12.4. Mobility in soil**

**Mobility in soil** : Not Available

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

**Results of PBT and vPvB assessment** : Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

**12.6. Other adverse effects**

**Environmental data** : Do not flush to sewer.

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

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

**SECTION 14: Transport information**

**14.1. UN number**

**UN number** : 3266

**14.2. UN proper shipping name**

**UN proper shipping name** : Corrosive liquid, basic inorganic, N.O.S. (Calcium hydroxide mixture)

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

**Hazard classification** : 8

**14.4. Packing group**

**Packing group** : III

**14.5. Environmental hazards**

**Marine pollutant #1** : NAP

**14.6. Special precautions for user**

**ADR - road** : NAP

**RID - rail** : NAP

**IMDG - sea** : NAP

**IATA - air** : NAP

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

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Transport in bulk : NAP

### SECTION 15: Regulatory information

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

**General comments** : Please refer to Medical Devices Directive 93/42/EEC.

#### 15.2. Chemical safety assessment

**Chemical safety assessment** : See Section 11

**Additional information** : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.

### SECTION 16: Other information

**Relevant R-phrases and/or H-statements (number and full text)** : R34: Causes burns.  
EYE DMG., Cat. 1: Eye Damage, Category 1  
STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Category 3  
Skin Irr., Cat. 2: Skin Irritation, Category 2  
H315: Causes skin irritation.  
H318: Causes serious eye damage.  
H335: May cause respiratory irritation.

**Prepared by** : Anu Kattoju

**Revision summary** : This SDS replaces the 09/29/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 3:** Wt.%. **Section 5:** EXTINGUISHING MEDIA, FIRE FIGHTING EQUIPMENT. **Section 8:** . **Section 9:** PHYSICAL STATE, SPECIFIC GRAVITY. **Section 11:** ACUTE ( DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat) ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information. **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.

**General statements** : NAP = Not Applicable  
NE = Not Established  
TLV = Threshold Limit Value  
PEL = Permittable exposure limits  
MAK = Maximum Workplace Concentration  
STEL = Short-term exposure limit  
STEV = Short-term exposure value  
TWA = Time Weighted Average  
PPE = Personal Protective Equipment

**Manufacturer disclaimer** : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and

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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.