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

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]
SAFETY DATA SHEET
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Hazard pictogram(s):
- Corrosive
- Exclamation mark

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.

Storage: P273: Avoid release to the environment.


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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Directive 67/548/EEC</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Hydroxide</td>
<td>1305-62-0</td>
<td>215-137-3</td>
<td>≤ 35</td>
<td>C; R34</td>
<td>Skin Irr.,Cat. 2; EYE DMG.,Cat. 1; STOT SE,Cat. 3; H315; H318; H335</td>
</tr>
<tr>
<td>Barium Sulfate</td>
<td>7727-43-7</td>
<td>231-784-4</td>
<td>≤ 20</td>
<td>Xi; R 36/38</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

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

SECTION 4: First aid measures

4.1. Description of first aid measures
UltraCal® XS

Following eyes
- 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.

Following skin
- Immediately flush skin with plenty of water. Remove clothing. Get medical attention immediately. Wash clothing separately before reuse.

Following ingestion
- 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.

Following inhalation
- 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

Eyes
- Causes severe eye damage.

Skin
- Irritating to skin.

Ingestion
- Ingestion of this material can cause mouth, throat, esophageal, and gastrointestinal tract irritation.

Inhalation
- None expected for this product.

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

Notes to physician
- Corrosive

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media
- 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

Hazardous combustion products
- None known.

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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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
- Clean up spills immediately, observing precautions in Protective Equipment section.

Large Spill
- Collect in tightly closed containers.

6.4. Reference to other sections

Reference to other sections
- Not Applicable
UltraCal® XS

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

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA Maritime Industry</td>
<td>15 mg/m³ TWA</td>
</tr>
<tr>
<td>OSHA General Industry</td>
<td>15 mg/m³ TWA</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>5mg/m³ TWA</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>5mg/m³ TWA</td>
</tr>
<tr>
<td>AIHA WHEEL</td>
<td>None</td>
</tr>
</tbody>
</table>

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

Canada

<table>
<thead>
<tr>
<th>Province</th>
<th>Control Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alberta</td>
<td>= 5mg/m³ TWA</td>
</tr>
<tr>
<td>British Columbia</td>
<td>= 5mg/m³ TWA</td>
</tr>
<tr>
<td>Ontario</td>
<td>= 5mg/m³ TWA</td>
</tr>
</tbody>
</table>
| Quebec         | = 5 mg/m³ TWA

Calcium Hydroxide CAS: 1305-62-0
Australia: 5mg/m³ TWA
Mexico: 5 mg/m³ TWA

Barium Sulfate CAS: 7727-43-7

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH TLV</td>
<td>10 mg/m³ TWA; The value is for particulate matter containing no asbestos and &lt; 1% crystalline Silica</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>10 mg/m³ TWA</td>
</tr>
</tbody>
</table>

8.2. Exposure controls
UltraCal® XS

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 LD₅₀: > 18000 mg/kg (Rabbit)
Notes: ~55% of the mixture consists of components of unknown toxicity (dermal).

Oral LD₅₀: > 1200 mg/kg (mouse/rat/rabbit)
Notes: There are no components of unknown toxicity (Oral).

Inhalation LC₅₀: 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.
### 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**


### 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**
UltraCal® XS

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 LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS. Section 12: CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, BIOACCUMULATION/ACUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), 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 = Permissible 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
UltraCal® XS

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.