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

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 : C
R phrases : R34

Classification according to Regulation(EC) No 1272/2008 [CLP]
Health : 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&S statement(s) : R34: Causes burns.

Classification according to Regulation(EC) No 1272/2008 [CLP]
UltraCal® XS

Hazard pictogram(s) : Corrosive Exclamation mark

Signal Word : DANGER

Hazard statement(s) : H318: Causes serious eye damage.
H315: Causes skin irritation.

Precautionary statement(s)


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): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P315: Get immediate medical advice/attention.
P363: Wash contaminated clothing before reuse.
P301: IF SWALLOWED:
P310: Immediately call a POISON CENTER or doctor/physician.
P330: Rinse mouth.
P331: Do NOT induce vomiting.

Storage : P273: Avoid release to the environment.


2.3. Other hazards

Immediate concerns : Corrosive

SECTION 3: Composition / information on ingredients

3.1. Substances
Not Applicable

3.2. Mixtures
UltraCal® XS

<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

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 immediately. Never give anything by mouth to an unconscious person.

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: Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products: None known.
UltraCal® XS

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
: Non-combustible.

 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

 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
: Not Determined

8.2. Exposure controls

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
: Paste
UltraCal® XS

9.2. Other information

- Colour: White to Off-White
- Odour: Odorless or no characteristic odor
- pH: 12.0 to 13.0

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 Notes: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity
- Toxicity: Not Determined
- Aquatic toxicity (acute): Do not allow to enter sewers or drains that may lead to waterways.
- 96-hour LC$_{50}$: Not Determined
- 48-hour EC$_{50}$: Not Determined
- 96-hour EC$_{50}$: Not Determined

12.2. Persistence and degradability
- Persistence and degradability: Not Determined

12.3. Bioaccumulative potential
- Bioaccumulative potential: Not Determined
12.4. Mobility in soil

Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Not Determined

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 : N/A

14.6. Special precautions for user

ADR - road : N/A

RID - rail : N/A

IMDG - sea : N/A

IATA - air : N/A

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

Transport in bulk : N/A

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
UltraCal® XS

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), Respiratory Tract 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 03/18/2015 SDS. Revised: Section 1: Section 2: Section 4: SIGNS AND SYMPTOMS OF OVEREXPOSURE (SKIN). Section 5: EXPLOSION HAZARDS, FIRE EXPLOSION, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. Section 12: ENVIRONMENTAL DATA, AQUATIC TOXICITY (ACUTE).

General statements:
N/A= Not Applicable

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.