

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 08/28/2012
 SDS No : 10-001.10
 Date Revised : 03/18/2015
 Revision No : 12

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

Distributor
 Ultrudent Products GmbH
 Am Westhoven 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 Corrosion, Category 2

2.2. Label elements

This mixture contains Calcium Hydroxide and Barium Sulfate. These materials are considered hazardous as defined by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : C



Corrosive

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

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



Date Issued : 08/28/2012
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UltraCal® XS

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

Hazard pictogram(s) :



Corrosive

Signal Word

: DANGER

Hazard statement(s)

: H314: Causes severe skin burns and eye damage.

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.
 P302: IF ON SKIN:
 P315: Get immediate medical advice/attention.
 P351: Rinse cautiously with water for several minutes.
 P362: Take off contaminated clothing and wash before reuse.
 P301: IF SWALLOWED:
 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.(EC 1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns : Corrosive

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

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



Date Issued : 08/28/2012
 SDS No : 10-001.10
 Date Revised : 03/18/2015
 Revision No : 12

UltraCal® XS

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	H318; H317; H412; H335; H314; H370; H290; H302; H312
Barium Sulfate	7727-43-7	231-784-4	≤ 20	Xi; R 36/38	H302; H332; H371; H319; H373; H335; H315

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 eye burns.

Skin : Causes skin burns.

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

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



Date Issued : 08/28/2012
 SDS No : 10-001.10
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UltraCal® XS

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.

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 : 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

SAFETY DATA SHEET
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 Dental Use



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 SDS No : 10-001.10
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 Revision No : 12

UltraCal® XS

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

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

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

SAFETY DATA SHEET
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UltraCal® XS

Aquatic toxicity (acute)

96-hour LC₅₀ : Not Determined
48-hour EC₅₀ : Not Determined
96-hour EC₅₀ : 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 : Biodegradability - Not established

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 : N/A

14.6. Special precautions for user

ADR - road : N/A

RID - rail : N/A

IMDG - sea : N/A

IATA - air : N/A

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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

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R34: Causes burns.
 H290: May be corrosive to metals.
 H302: Harmful if swallowed.
 H312: Harmful in contact with skin.
 H314: Causes severe skin burns and eye damage.
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H318: Causes serious eye damage.
 H319: Causes serious eye irritation.
 H332: Harmful if inhaled.
 H335: May cause respiratory irritation.
 H370: Causes damage to organs .
 H371: May cause damage to organs .
 H373: May cause damage to organs through prolonged or repeated exposure .
 H412: Harmful to aquatic life with long lasting effects.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 02/27/2015 SDS. Revised: **Section 1: . Section 2: . Section 8: PERSONAL PROTECTIVE EQUIPMENT - SKIN. Section 16: GENERAL STATEMENTS.**

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.