

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 8/28/2012

SDS No : 10-001.8

Date Revised : 8/7/2014

Revision No : 10

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 : Endodontics 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

Danger symbols : C
R phrases : R34

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]

Hazard pictogram(s) :

Corrosive

Signal Word : DANGER

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Hazard statement(s) : H314: Causes severe skin burns and eye damage.

2.3. Other hazards

Immediate concerns : Corrosive

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
Calcium Hydroxide	1305-62-0	215-137-3	35	C; R34
Barium Sulfate	7727-43-7	231-784-4	20	Xi; R 36/38

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

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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.

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) : Endodontic Paste

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

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8.2. Exposure controls

- Eye/face protection** : Wear safety glasses with side shields (or goggles) and a face shield.
- Skin protection** : S36/37: 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 Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

- Stable** : Yes

10.2. Chemical stability

- Chemical stability** : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

- Hazardous polymerization** : No

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** : Not Determined
- Oral LD₅₀** : Not Determined
- Inhalation LC₅₀** : Not Determined

SECTION 12: Ecological information

12.1. Toxicity

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Toxicity : Not yet Determined

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

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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 : Not Determined

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R34: Causes burns.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 9/26/2012 SDS. Revised: **Section 1:** GENERAL USE. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 4:** INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE (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:** SHELF LIFE, STORAGE, . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY. **Section 9:** COLOR, PERCENT VOLATILE. **Section 10:** HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat)). **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14:** AIR (ICAO/IATA) (SPECIAL PROVISIONS), ROAD AND RAIL (ADR/RID) (UN NUMBER), VESSEL (IMO/IMDG) (SPECIAL PROVISIONS), ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS. **Section 15:** RoHS, SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.

General statements : NA = Not Applicable

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

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