

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



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]

SAFETY DATA SHEET

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



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

UltraCal® XS

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

SAFETY DATA SHEET

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



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

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
------------------------------------	------------------

SAFETY DATA SHEET

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



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

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

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

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

Alberta	= 5mg/m ³ TWA
British Columbia	= 5mg/m ³ TWA
Ontario	= 5mg/m ³ TWA
Quebec	= 5 mg/m ³ TWAEV

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

Barium Sulfate CAS: 7727-43-7

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

8.2. Exposure controls

SAFETY DATA SHEET

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



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

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.

SAFETY DATA SHEET

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



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

UltraCal® XS

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

SAFETY DATA SHEET

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



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

UltraCal® XS

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 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/ACCUMULATION, 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 = 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

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



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

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.