

safety data sheet

to product

Ultradent UltraCal XS syringe Kit

1. Identification of the substance / preparation and company

Emergency number:

Tox Info Suisse, Freiestrasse 16, 8032 Zürich; Tox-Info Suisse: 145 (24h-operation); info@toxinfo.ch;
In case of emergency: Tel. 145; (abroad: +41 44 251 51 51); information: +41 44 251 66 66

Company name:



abc dental ag

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Condor Dental Research CO Sàrl

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Tel. 024 482 61 61, Fax 024 482 61 69



Curaden AG Dentaldepot

Riedstrasse 12, 8953 Dietikon
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dema dent AG

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Flexdental Services SA

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Kaladent AG

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Smart Dentist AG

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Safety Data Sheet
acc. to OSHA HCS

Printing date 09/02/2021

Reviewed on 10/14/2020

1 Identification

- **Product identifier**
- **Trade name:** UltraCal™ XS
- **Article number:** SDS 10-001.13, 41711
- **Index number:** SDS 10-001.13
- **Application of the substance / the mixture** Professional Dental Cavity Liner
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com
- **Information department:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS05 Corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** GHS05
- **Signal word** Danger
- **Health Hazard-determining components of labeling:**
Calcium Hydroxide
- **Hazard statements**
Causes severe skin burns and eye damage.
- **Precautionary statements**
P260 Do not breathe dusts or mists.
P264 Wash thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331 If swallowed: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a poison center/doctor.
P321 Specific treatment (see on this label).
P363 Wash contaminated clothing before reuse.

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P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

1305-62-0	Calcium Hydroxide	☠ Eye Dam. 1, H318	≥3-<40%
7727-43-7	Barium Sulfate		>10-≤25%
57-55-6	Propylene Glycol		1-10%

4 First-aid measures

- **Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
 This product is a thick paste, therefore inhalation is extremely unlikely.
 In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Drink copious amounts of water and provide fresh air. Immediately call a doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
 No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture**
 During heating or in case of fire poisonous gases are produced.
- **Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**

Mount respiratory protective device.

Wear protective equipment. Keep unprotected persons away.

- **Environmental precautions:**

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

- **Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Use neutralizing agent.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

- **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

- **Handling:**

- **Precautions for safe handling**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- **Information about protection against explosions and fires:** Keep respiratory protective device available.

- **Conditions for safe storage, including any incompatibilities**

- **Storage:**

- **Requirements to be met by storerooms and receptacles:** No special requirements.

- **Information about storage in one common storage facility:** Not required.

- **Further information about storage conditions:**

See product labelling.

Keep receptacle tightly sealed.

- **Specific end use(s)** Professional Dental Cavity Liner

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

1305-62-0 Calcium Hydroxide

PEL Long-term value: 15* 5** mg/m³
*total dust **respirable fraction

REL Long-term value: 5 mg/m³

TLV Long-term value: 5 mg/m³

7727-43-7 Barium Sulfate

PEL Long-term value: 15* 5** mg/m³
*total dust **respirable fraction

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REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	Long-term value: 5* mg/m ³ *inhalable fraction; E
57-55-6 Propylene Glycol	
WEEL	Long-term value: 10 mg/m ³

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes.

Avoid contact with the eyes and skin.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material is based on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Paste

Color: White to Off-White

· **Odor:** Odorless

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· Odor threshold:	Not determined.
· pH-value at 20 °C:	12-13
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined
· Flash point:	Not applicable
· Flammability (solid, gaseous):	Not applicable.
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density at 20 °C:	1.4-1.5 g/cm ³
· Relative density	Not determined
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
Water:	Fully miscible.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined
· Solvent content:	
Organic solvents:	5.0 %
Water:	39.3 %
VOC content:	5.00 %
	70-75 g/l / 0.58-0.63 lb/gal
VOC (EC)	5.00 %
Solids content:	<60.0 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

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11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

1305-62-0 Calcium Hydroxide		
Oral	LD50	7,340 mg/kg (rat)
7727-43-7 Barium Sulfate		
Oral	LD50	>3,000 mg/kg (mouse) 307,000 mg/kg (rat)
57-55-6 Propylene Glycol		
Oral	LD50	18,000 mg/kg (rabbit)
	LC50 Fish	>5,000 mg/l (Fish)
Dermal	LD50	20,800 mg/kg (rabbit)

- **Primary irritant effect:**

- **on the skin:** Strong caustic effect on skin and mucous membranes.

- **on the eye:**

- Strong caustic effect.

- Strong irritant with the danger of severe eye injury.

- **Sensitization:** No sensitizing effects known.

- **Additional toxicological information:**

- The product shows the following dangers according to internally approved calculation methods for preparations:

- Corrosive

- Irritant

- Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

- None of the ingredients is listed.

- **NTP (National Toxicology Program)**

- None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

- None of the ingredients is listed.

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

7727-43-7 Barium Sulfate		
EC50	32 mg/kg (daphnia)	
57-55-6 Propylene Glycol		
EC50	18,100 mg/kg (Algae)	

- **Persistence and degradability** No further relevant information available.

- **Behavior in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.

- **Mobility in soil** No further relevant information available.

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- **Additional ecological information:**

- **General notes:**

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Must not reach bodies of water or drainage ditch undiluted or unneutralized.

Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**

- **Recommendation:**

Do not allow product to reach sewage system.

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- **Uncleaned packagings:**

- **Recommendation:** Disposal must be made according to official regulations.

- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- **UN-Number**

- **DOT, IMDG, IATA**

UN1719

- **UN proper shipping name**

- **DOT**

- **IMDG, IATA**

Caustic alkali liquids, n.o.s. (Calcium Hydroxide)

CAUSTIC ALKALI LIQUID, N.O.S.

- **Transport hazard class(es)**

- **DOT**



- **Class**

8 Corrosive substances

- **Label**

8

- **IMDG, IATA**



- **Class**

8 Corrosive substances

- **Label**

8

- **Packing group**

- **DOT**

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· Environmental hazards:	Not Applicable.
· Special precautions for user	Warning: Corrosive substances
· EMS Number:	F-A,S-B
· Segregation groups	Alkalis
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not Applicable.
· Transport/Additional information:	
· DOT	
· Quantity limitations	On passenger aircraft/rail: No limit On cargo aircraft only: No limit
· UN "Model Regulation":	UN 1719 CAUSTIC ALKALI LIQUID, N.O.S., 8, II

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

7727-43-7 Barium Sulfate

· **TSCA (Toxic Substances Control Act):**

All components have the value ACTIVE.

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

7727-43-7 Barium Sulfate

D, CBD(inh), NL(oral)

· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

1309-48-4 Magnesium Oxide

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

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· **Chemical safety assessment:**

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

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **Date of preparation / last revision** 09/02/2021 / -

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

US