

Safety data sheet according to UK REACH

Printing date 12.09.2025

Version number 1

Revision: 12.09.2025

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** UltraCal™ XS
- **Article number:**
SDS 10-001.14R01, 41711, 41716, 1024, 5144, 5144-JP, 5145, 5145-CE, 5145-JP, 5149, 5149-I, 606-P3
- **Relevant identified uses of the substance or mixture and uses advised against** Professional Dental Cavity Liner
- **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
(800) 552-5512
- **EC Responsible Person**
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Office Phone: +49(0)2203-35-92-0
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



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

Eye Dam. 1 H318 Causes serious eye damage.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** GHS05
- **Signal word** Danger
- **Hazard-determining components of labelling:**
Calcium Hydroxide
- **Hazard statements**
H314 Causes severe skin burns and eye damage.
- **Precautionary statements**
P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
P103 Read carefully and follow all instructions.

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- P260 Do not breathe dusts or mists.
 P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
 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).
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 1305-62-0 EINECS: 215-137-3	Calcium Hydroxide	☞ Eye Dam. 1, H318	≥3-<40%
CAS: 7727-43-7 EINECS: 231-784-4	Barium Sulfate	substance with a Community workplace exposure limit	>10-≤25%
CAS: 57-55-6 EINECS: 200-338-0	Propylene Glycol	substance with a Community workplace exposure limit	1-10%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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 plenty of water and provide fresh air. Call for a doctor immediately.
- **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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **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 neutralising agent.

Dispose contaminated material as waste according to section 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

- **Precautions for safe handling:**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- **Information about fire - and explosion protection:** 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 container tightly sealed.

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

8 Exposure controls/personal protection

- **Control parameters**

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

1305-62-0 Calcium Hydroxide

WEL Short-term value: 4* mg/m³

Long-term value: 5 1* mg/m³

*resprable fraction

7727-43-7 Barium Sulfate

WEL Long-term value: 10* 4** mg/m³

*inhalable dust **respirable dust

57-55-6 Propylene Glycol

WEL Long-term value: 474* 10** mg/m³, 150* ppm

*total vapour and particulates **particulates

- **Additional information:** The lists valid during the making were used as basis.

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- **Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as 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.
- **Respiratory protection:**
 In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Hand protection**



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 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/face protection**



Tightly sealed goggles

- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Fluid
- **Colour:** White to off white
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Decomposition temperature:** Not determined.

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· pH at 20 °C	12-13
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	1.4-1.5 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.

· Other information	
· Appearance:	
· Form:	Paste
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not determined.

· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

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.

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· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

· **Information on hazard classes as defined in Regulation (EC) No 1272/2008**· **Acute toxicity** Based on available data, the classification criteria are not met.· **LD/LC50 values relevant for classification:**

1305-62-0 Calcium Hydroxide

Oral	LD50	7,340 mg/kg (rat)
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7727-43-7 Barium Sulfate

Oral	LD50	>3,000 mg/kg (mouse) 307,000 mg/kg (rat)
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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:**· **Skin corrosion/irritation** Causes severe skin burns and eye damage.· **Serious eye damage/irritation** Causes serious eye damage.· **Information on other hazards**· **Endocrine disrupting properties**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**· **Aquatic toxicity:**

7727-43-7 Barium Sulfate

EC50	32 mg/kg (daphnia)
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57-55-6 Propylene Glycol

EC50	18,100 mg/kg (Algae)
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· **Persistence and degradability** No further relevant information available.· **Bioaccumulative potential** No further relevant information available.· **Mobility in soil** No further relevant information available.· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.· **Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.· **Other adverse effects**· **Additional ecological information:**· **General notes:**

Water hazard class 1 (German Regulation) (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 sewage water or drainage ditch undiluted or unneutralised.

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.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Do not allow product to reach sewage system.
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
Dispose of contents/container in accordance with international, federal, state, and local regulations.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· UN number or ID number · ADR, IMDG, IATA	UNI719
· UN proper shipping name · ADR · IMDG, IATA	1719 CAUSTIC ALKALI LIQUID, N.O.S. CAUSTIC ALKALI LIQUID, N.O.S.
· Transport hazard class(es) · ADR, IMDG, IATA	
	
· Class · Label	8 Corrosive substances. 8
· Packing group · ADR	II
· Environmental hazards:	Not applicable.
· Special precautions for user · EMS Number: · Segregation groups	Warning: Corrosive substances. F-A,S-B (SGG18) Alkalis
· Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1719 CAUSTIC ALKALI LIQUID, N.O.S. 8, II

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15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

None of the ingredients is listed.

· **Poisons Act**

· **Regulated explosives precursors**

None of the ingredients is listed.

· **Regulated poisons**

None of the ingredients is listed.

· **Reportable explosives precursors**

None of the ingredients is listed.

· **Reportable poisons**

None of the ingredients is listed.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **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.

· **Relevant phrases from Section 3**

H318 Causes serious eye damage.

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

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

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

ATE: Acute toxicity estimate values

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

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

· *** Data compared to the previous version altered.**