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

- **Product identifier**
  - **Trade name:** UltraCal™ XS
  - **Article number:** 41711
  - **Index number:** SDS 10-001.13
  - **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@utradent.com
  - **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
  - **Further information obtainable from:** Customer Service
  - **Emergency telephone number:**
    - CHEMTREC (NORTH AMERICA) : (800) 424-9300
    - (INTERNATIONAL) : +(703) 527-3887

Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
  - **GHS05 corrosion**
  - **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**
  - The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
- **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.
Trade name: UltraCal™ XS

P102 Keep out of reach of children.
P103 Read label before use.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/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.

Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.
vPvB: Not applicable.

3 Composition/information on ingredients

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

- Dangerous components:

<table>
<thead>
<tr>
<th>CAS Code</th>
<th>Substance Description</th>
<th>Community workplace exposure limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1305-62-0</td>
<td>Calcium Hydroxide</td>
<td>≤35%</td>
</tr>
<tr>
<td>7727-43-7</td>
<td>Barium Sulfate</td>
<td>≤20%</td>
</tr>
<tr>
<td>57-55-6</td>
<td>Propylene Glycol</td>
<td>≤5%</td>
</tr>
</tbody>
</table>

- 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.
- 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.
- 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 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.
Trade name: UltraCal™ XS

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 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 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

- Additional information about design of technical facilities: No further data; see item 7.
- Control parameters

<table>
<thead>
<tr>
<th>Ingredients with limit values that require monitoring at the workplace:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1305-62-0 Calcium Hydroxide</td>
</tr>
<tr>
<td>WEL (Great Britain)</td>
</tr>
<tr>
<td>Short-term value: 4* mg/m³</td>
</tr>
<tr>
<td>Long-term value: 5 1* mg/m³</td>
</tr>
<tr>
<td>*respirable fraction</td>
</tr>
<tr>
<td>7727-43-7 Barium Sulfate</td>
</tr>
<tr>
<td>WEL (Great Britain)</td>
</tr>
<tr>
<td>Long-term value: 10* 4** mg/m³</td>
</tr>
<tr>
<td>*inhalable dust **respirable dust</td>
</tr>
</tbody>
</table>

(Contd. of page 2)
Additional information: The lists valid during the making 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.

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.

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 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
Colour: White to Off-White
Odour: Odourless
Odour threshold: Not determined.
pH-value at 20 °C: 12-13
### 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.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**: Based on available data, the classification criteria are not met.
Trade name: UltraCal™ XS

48.0 · LD/LC50 values 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:
- Skin corrosion/irritation: Causes severe skin burns and eye damage.
- Serious eye damage/irritation: Causes serious eye damage.
- Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.
- CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
  - Germ cell mutagenicity: Based on available data, the classification criteria are not met.
  - Carcinogenicity: Based on available data, the classification criteria are not met.
  - Reproductive toxicity: Based on available data, the classification criteria are not met.
  - STOT-single exposure: Based on available data, the classification criteria are not met.
  - STOT-repeated exposure: Based on available data, the classification criteria are not met.
  - Aspiration hazard: Based on available data, the classification criteria are not met.

12 Ecological information

Toxicity

- **Aquatic toxicity:**
  - **7727-43-7 Barium Sulfate**
    - EC50: 32 mg/l (daphnia)
  - **57-55-6 Propylene Glycol**
    - EC50: 18,100 mg/l (Algae)
    - >100,000 mg/l (daphnia)

Persistence and degradability: No further relevant information available.

Behaviour in environmental systems:
- Bioaccumulative potential: No further relevant information available.
- Mobility in soil: No further relevant information available.

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.

Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.
13 Disposal considerations

- Waste treatment methods
- Recommendation Do not allow product to reach sewage system.

- European waste catalogue
  - HP 4 Irritant - skin irritation and eye damage

- 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
  - ADR, IMDG, IATA UN1719

- UN proper shipping name
  - ADR 1719 CAUSTIC ALKALI LIQUID, N.O.S. (Calcium Hydroxide)
  - IMDG, IATA CAUSTIC ALKALI LIQUID, N.O.S. (Calcium Hydroxide)

- Transport hazard class(es)
  - ADR, IMDG, IATA
    - Class 8 Corrosive substances.

- Packing group
  - ADR II

- Environmental hazards:
  - Not applicable.

- Special precautions for user
  - EMS Number: Warning: Corrosive substances.
  - Segregation groups Alkalis
  - Stowage Category A
  - Segregation Code SG22 Stow "away from" ammonium salts
  - SG33 Stow "separated from" acids.

- Transport in bulk according to Annex II of Marpol and the IBC Code
  - Not applicable.

- Transport/Additional information:
  - ADR
    - Limited quantities (LQ) 1L
    - Excepted quantities (EQ) Code: E2
      - Maximum net quantity per inner packaging: 30 ml
      - Maximum net quantity per outer packaging: 50 ml
15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
  - 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
  H318 Causes serious eye damage.

- Department issuing SDS: Regulatory Affairs
- Contact: Customer Service

- Abbreviations and acronyms:
  ADR: Accord européen sur le transport 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)
  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
  Skin Corr. 1A: Skin corrosion/irritation – Category 1A
  Eye Dam. 1: Serious eye damage/eye irritation – Category 1