Safety Data Sheet

Trade Names:
Calcium Hydroxide Preparations: Cavity Liner, Multi-Cal, Pulpdent Paste, TempCanal, Calcium Hydroxide Powder USP

1.0 Commercial Product Name and Supplier

1.1 Commercial product name / designation

CALKUM HYDROXIDE PRODUCTS
- Cavity Liner
- Multi-Cal
- Pulpdent Paste
- TempCanal
- Calcium Hydroxide Powder, USP

1.2 Application / Use

Dental material for use by dental professionals.

1.2.2 SIC

851 Human health activity

1.3 Manufacturer

Pulpdent Corporation
80 Oakland Street, P.O. Box 780
Watertown, MA 02472  USA

Telephone: 1 617 926-6666
Fax: 1 617 926-6262
Email: Pulpdent@pulpdent.com

1.4 Emergency Telephone Number

1-800-535-5053 (24 Hour / USA)

1.5 Authorized European Representative

International Business Solutions Ltd.
54 Mayfield Ridge, Hatch Warren,
Basingstoke, RG22 4RS UK

Tel: 07989 407479 / Fax: 01256 350330
Email: s.williams5@btconnect.co.uk

2.0 Hazards Identification

2.1 Classification

2.1.1 Classification according to Regulation (EC) No. 1272/2008 [CLP]

<table>
<thead>
<tr>
<th>Product</th>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavity Liner</td>
<td>Skin irritation</td>
<td>2</td>
<td>H315</td>
</tr>
<tr>
<td></td>
<td>Eye irritation</td>
<td>2</td>
<td>H319</td>
</tr>
<tr>
<td>Multi-Cal</td>
<td>Skin irritation</td>
<td>2</td>
<td>H315</td>
</tr>
<tr>
<td></td>
<td>Eye irritation</td>
<td>2</td>
<td>H319</td>
</tr>
<tr>
<td>Pulpdent Paste</td>
<td>Skin irritation</td>
<td>2</td>
<td>H315</td>
</tr>
<tr>
<td></td>
<td>Eye irritation</td>
<td>2</td>
<td>H319</td>
</tr>
<tr>
<td>TempCanal</td>
<td>Skin irritation</td>
<td>2</td>
<td>H315</td>
</tr>
<tr>
<td></td>
<td>Eye irritation</td>
<td>2</td>
<td>H319</td>
</tr>
<tr>
<td>Calcium Hydroxide Powder, USP</td>
<td>Skin irritation</td>
<td>2</td>
<td>H315</td>
</tr>
<tr>
<td></td>
<td>STOT SE</td>
<td>2</td>
<td>H335</td>
</tr>
<tr>
<td></td>
<td>Eye irritation</td>
<td>2</td>
<td>H319</td>
</tr>
</tbody>
</table>
Safety Data Sheet

Trade Names:
Calcium Hydroxide Preparations: Cavity Liner, Multi-Cal, Pulpdent Paste, TempCanal, Calcium Hydroxide Powder USP

2.1.2 Classification according to Directive 67/548/EEC
(See SECTION 16 for full text of risk phrases)
Irritant (Xi); R 36 / 37 / 38

2.1.3 Classification according to WHMIS
D2: Irritant

2.2 GHS Label Elements

Hazard Pictograms

Signal Word: WARNING
Restricted to use by dental professional only.

Hazard Statements
H319: Eye irritation. 2. May cause eye irritation.
H315: Skin irritation. 2. May cause skin irritation.
H335: STOT SE. 3. May cause respiratory irritation. (Calcium hydroxide powder only)

Precautionary Statements
P280: Wear protective gloves and eye protection
P305+P351: If in eyes, rinse cautiously with water for several minutes.
P337+P313: If eye irritation persists, get medical advice/attention.
P302+P352: If on skin, wash with plenty of soap and water.
P261: Avoid breathing dust. (Calcium hydroxide powder only)

3.0 Composition

3.1 Chemical characterization of the preparation
Paste, Multi-Cal, TempCanal, Cavity Liner: Calcium hydroxide suspended in a cellulose/water gel matrix.
Calcium Hydroxide Powder USP: Calcium hydroxide powder only.

3.2 Hazardous ingredients

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Name of the Ingredient</th>
<th>Concentration</th>
<th>Classification per 67/548/EEC</th>
<th>Classification per Regulation (EC) No.1278/2008 (CLP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1305-62-0</td>
<td>Calcium Hydroxide</td>
<td>Cavity Liner: 32%</td>
<td>Irritant (Xi)</td>
<td>Skin irritation; 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R 36 / 38</td>
<td>Eye irritation; 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Multi-Cal: 42%</td>
<td>Irritant (Xi)</td>
<td>Skin irritation; 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R 36 / 38</td>
<td>Eye irritation; 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pulpdent Paste: 42%</td>
<td>Irritant (Xi)</td>
<td>Skin irritation; 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R 36 / 38</td>
<td>Eye irritation; 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TempCanal: 39%</td>
<td>Irritant (Xi)</td>
<td>Skin irritation; 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R 36 / 38</td>
<td>Eye irritation; 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Calcium Hydroxide Powder: 100%</td>
<td>Irritant (Xi)</td>
<td>Skin irritation; 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R 36 / 37 / 38</td>
<td>STOT SE; 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye irritation; 2</td>
</tr>
</tbody>
</table>
## Safety Data Sheet

**Trade Names:**
Calcium Hydroxide Preparations: Cavity Liner, Multi-Cal, Pulpdent Paste, TempCanal, Calcium Hydroxide Powder USP

### 4.0 First Aid Measures

| 4.1 | Special Instructions | Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty. The calcium hydroxide-based products listed above present minimal hazard in the quantities of liquid and paste provided. Only with prolonged exposure are these products irritating to mucous membranes, eyes, skin, gastrointestinal tract or respiratory tract. Calcium hydroxide powder presents an inhalation hazard if allowed to disperse. |
| 4.2 | Eye Contact | Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention. |
| 4.3 | Skin Contact | Remove any contaminated clothing. Wipe off excess from skin. Immediately flush skin water. Get medical attention if irritation persists. |
| 4.4 | Ingestion | Rinse mouth with water. Do not induce vomiting. Give large amounts of water to dilute. Get immediate medical attention for ingestion of large amount. Never give anything by mouth to an unconscious person. |
| 4.5 | Inhalation | Move to fresh air. If necessary, administer artificial respiration and seek medical attention. |
| 4.6 | Precautions for first responders | Wear safety glasses and gloves to prevent contact. Wear a dust mask if the powder form has dispersed. |
| 4.7 | Information for physician | **Symptoms** Irritation, pain or redness in eyes, on skin, on mucous membranes. **Hazards** May be irritating to eyes, skin, respiratory system, gastrointestinal tract or mucous membranes especially with prolonged exposure There is a risk of serious damage to eyes. Calcium hydroxide powder presents an inhalation hazard if allowed to disperse. **Treatment** Same as First Aid above. |

### 5.0 Fire Fighting Measures

| 5.1 | Suitable extinguishing media | Not a fire hazard. Extinguish fire with agent suitable for surrounding fire. |
| 5.2 | Extinguishing media to avoid | None |
| 5.3 | Special exposure hazards in a fire | None |
| 5.4 | Special protective equipment for fire-fighters | Self-contained breathing apparatus |

### 6.0 Accidental Release Measures

| 6.1 | Personal precautions. | Wear gloves, lab coat and chemical splash goggles. |
| 6.2 | Environmental precautions | None |
Safety Data Sheet

Trade Names:
Calcium Hydroxide Preparations: Cavity Liner, Multi-Cal, Pulpdent Paste, TempCanal, Calcium Hydroxide Powder USP

6.3 Method for clean up
For powder spills, wear dust mask; pick up spilled material without dispersing powder into air.
For paste and liquid spills, wipe up or absorb with paper towel. Wash area of spill with water-saturated paper towels or cloths. Place spilled material and absorbent towels in container for disposal.

7.0 Handling and Storage

7.1 Handling
For use by dental professionals only. Wear gloves, safety glasses; wash hands after use. Avoid unnecessary exposure. Follow good hygiene practices. Do not smoke, eat or drink. Wash hands after use.

7.2 Storage
Remove applicator tip immediately after use. Keep tightly capped in original container. Store at cool room temperature. Avoid extremes of temperature (>27°C/80°F, <5°C/40°F) and acids.

7.3 Specific uses
Dental preparations

8.0 Exposure Controls / Personal Protection

8.1 Exposure limit values
Calcium Hydroxide Powder only: PEL / TLV 5 mg/m³

8.2 Exposure controls
Wear safety glasses, lab coat and gloves. No other equipment required under normal conditions of use of this product in the quantity provided.

8.2.1 Occupational exposure controls
Wear safety glasses, lab coat and gloves. No other equipment required under normal conditions of use of this product in the quantity provided.

8.2.1.1 Respiratory protection
Powdered Calcium Hydroxide: None under normal conditions of dental practice. For large quantities, > PEL/TLV, OSHA-approved dust mask.
Paste and liquid preparations: Good general ventilation is sufficient to control any airborne vapors.

8.2.1.2 Hand protection
No special requirements. The usual surgical gloves worn by dental staff will limit contact with this material.

8.2.1.3 Eye protection
No special requirements other than the usual safety glasses worn by dental staff.

8.2.1.4 Skin protection
No special requirements. Good personal hygiene and safety practices and wearing a lab coat should protect dental staff from unnecessary exposure.

8.2.1.5 Other controls
Emergency eye wash fountain should be close by and maintained. Wash hands after use.

8.2.2 Environmental exposure controls
Avoid release into environment as calcium hydroxide may cause pH variation.

9.0 Physical and Chemical Properties

9.1 Appearance / Color
Cavity Liner: White liquid
Multi-Cal: White paste
Pulpdent Paste: White paste
TempCanal: White paste
Calcium Hydroxide Powder USP: White powder
Safety Data Sheet

Trade Names:
Calcium Hydroxide Preparations: Cavity Liner, Multi-Cal, Pulpdent Paste, TempCanal, Calcium Hydroxide Powder USP

9.1.2 Odor Odorless

9.2 Important health, safety and environmental information

9.2.1 pH pH > 12

9.2.2 Boiling point Decomposes

9.2.3 Flash point Not combustible

9.2.4 Flammability (solid, gas) Not combustible

9.2.5 Explosive properties Not applicable

9.2.6 Oxidizing properties Not determined

9.2.7 Vapor pressure Cavity Liner, Multi-Cal, Paste, TempCanal: < 1 mm Hg (Id: A)
Calcium hydroxide powder: Not applicable

9.2.8 Specific gravity Not determined

9.2.9 Solubility in water Slight

9.2.10 Partition coefficient Not determined

9.2.11 Viscosity Not determined

9.2.12 Vapor density Not determined

9.2.13 Evaporation rate Not determined

10.0 Stability and reactivity

10.1 Conditions to avoid Extremes of temperature (>27°C/80°F, <5°C/40°F).

10.2 Materials to avoid Calcium hydroxide reacts violently with maleic anhydride, nitro-ethane, nitro-methane, nitro-paraffin, nitro-propane, phosphorus. As a strong alkali, it is incompatible with acids.

10.3 Hazardous decomposition products Caustic fumes of calcium oxide when heated to decomposition.

10.4 Further information Stable under normal conditions.

11.0 Toxicological information

11.1 Acute toxicity Not toxic. Minimal health hazard under normal conditions of use.

11.2 Irritation and corrosiveness Minimal health hazard under normal conditions of dental practice. Prolonged exposure may cause irritation of mucous membranes, eyes, skin, gastrointestinal tract or respiratory tract. Calcium hydroxide powder may present an inhalation hazard.

11.3 Sensitization Not applicable.

11.4 Sub-acute, sub-chronic and prolonged toxicity Narrowing of the esophagus may occur weeks to years after ingestion of large quantities, making swallowing difficult. Persons with pre-existing skin conditions may be more susceptible to the irritating effects of calcium hydroxide

11.5 Carcinogenicity, Mutagenicity, Reproductive Toxicity Not considered a carcinogen, mutagen or teratogen. Not toxic to the reproductive system.

11.6 Empirical data Not available
Safety Data Sheet

Trade Names:
Calcium Hydroxide Preparations: Cavity Liner, Multi-Cal, Pulpdent Paste, TempCanal, Calcium Hydroxide Powder USP

11.7 Clinical Experience
Pulpdent calcium hydroxide preparations have been marketed to and used by dental professionals since 1947. Dentists’ experience with thousands of successful procedures is evidence of safe and effective dental treatment.

12.0 Ecological Information
12.1 Ecotoxicity
Not considered detrimental to water or soil. Avoid release into environment as calcium hydroxide may cause pH variation. Follow government regulations.

13.0 Disposal Considerations
13.1 Regulations
Follow all local and national government regulations in disposing material or contaminated packaging.

14.0 Transport Information
14.1 Restrictions
None. Not regulated.

14.2 UN Number
None

14.3 Technical name
Calcium hydroxide preparation

14.4 Packing group
Not applicable

IATA class
Not applicable

15.0 Regulatory Information
15.1 EU Regulations
Pulpdent Paste, Cavity Liner, TempCanal, Multi-Cal are Class IIa Medical Devices under the Medical Devices Directive 93/42/EEC.

15.2 US FDA
Class II medical devices

15.3 Canada Regulation
Pulpdent Paste, Cavity Liner, TempCanal, Multi-Cal, and Calcium hydroxide powder have been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

16.0 Other information
16.1 List of relevant R phrases
R36/38: Irritating to eyes and skin.
R36/37/38: Irritating to eyes, respiratory system and skin (Calcium hydroxide powder only).

16.2 Hazard Statements
H319: Eye irritation. 2. May cause eye irritation.
H315: Skin irritation. 2. May cause skin irritation.
H335: STOT SE. 3. May cause respiratory irritation. (Calcium hydroxide powder only)

16.3 Precautionary Statements
P280: Wear protective gloves and eye protection
P305+P351: If in eyes, rinse cautiously with water for several minutes.
P337+P313: If eye irritation persists, get medical advice/attention.
P302+P352: If on skin, wash with plenty of soap and water.
P261: Avoid breathing dust. (Calcium hydroxide powder only)
## Safety Data Sheet

### Trade Names:
Calcium Hydroxide Preparations: *Cavity Liner, Multi-Cal, Pulpdent Paste, TempCanal, Calcium Hydroxide Powder USP*

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>16.4</td>
<td>Restrictions on use</td>
<td>Calcium hydroxide preparations are to be used only by dental professionals who have been trained in their use.</td>
</tr>
<tr>
<td>16.5</td>
<td>Further information</td>
<td>The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.</td>
</tr>
</tbody>
</table>
| 16.6    | Sources of key data | National Institute for Occupational Safety (NIOSH)  
Occupational Safety and Health Administration (OSHA)  
| 16.7    | Information which has been added, deleted or revised. | This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified. |