

# SAFETY DATA SHEETS

**This SDS packet was issued with item:**

075898150

N/A

**MATERIAL SAFETY DATA SHEET: CALCIUM HYDROXIDE PRODUCTS**

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<b>IDENTITY:</b>	<i>Trade Name</i>	<i>Code:</i>
	Cavity Liner	PCL
	<b>Multi-Cal</b>	MULTI, MULTI-3
	Pulpdent Paste	PSYK, PSY, PSYN
	TempCanal	PTCK, PTC
	Calcium Hydroxide Powder	CH4, CH16

*Chemical Description:* Calcium hydroxide preparation

*Product Use:* Dental material

**SECTION I**

*Pulpdent Corporation*

80 Oakland Street

Watertown, MA 02472 USA

Date Prepared: September 1, 2008

*Phone Numbers:*

24 Hour Emergency: (800) 535-5053

Customer Service: (800) 343-4342 / 617-926-6666

**SECTION II - HAZARDOUS INGREDIENTS**

<i>Ingredient</i>	<i>CAS RN</i>	<i>PEL/TLV</i>
Calcium Hydroxide	1305-62-0	5 mg/m <sup>3</sup>

DOT HAZARD CLASSIFICATION: Not regulated

WHMIS CLASSIFICATION: E - Corrosive material

NFPA HMIS RATING: HEALTH: 1 FLAMMABILITY: 0 REACTIVITY: 1

**SECTION III - PHYSICAL / CHEMICAL CHARACTERISTICS**

Boiling Point: Decomposes Melting Point: 580°C

Solubility in water: Negligible Odor Threshold: Not available

Appearance: White liquid, paste or powder Odor: Odorless

**SECTION IV - FIRE AND EXPLOSION HAZARD DATA**

Flash Point: Not available Flammable limits: Not available

Extinguishing Media: Use any means suitable for extinguishing surrounding fire.

Special Fire Fighting Procedures: Wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode.

Hazardous combustion products: Caustic fumes of calcium oxide form when heated to decomposition.

Unusual Fire and Explosion Hazards: None

**SECTION V - REACTIVITY DATA**

Stability: Stable under normal conditions. Conditions to avoid: Excessive heat.

Incompatibility: Material reacts violently with maleic anhydride, nitroethane, nitromethane, nitroparaffins, nitropropane and phosphorus. As a strong alkali, it is incompatible with acids.

Hazardous Decomposition Products: Caustic fumes of calcium oxide when heated to decomposition.

Hazardous Polymerization: Will not occur. Conditions to avoid: None.

**SECTION VI - HEALTH HAZARD DATA**

*Summary of Acute Hazards:* Minimal health hazard in the quantity of liquid and paste contained in these products and under normal conditions of use. However, in large amounts and/or with prolonged exposure, calcium hydroxide is corrosive and may cause irritation and burns to mucous membranes, eyes, gastrointestinal tract, respiratory tract and skin. Calcium hydroxide in its powdered form presents an inhalation hazard.

**MATERIAL SAFETY DATA SHEET: CALCIUM HYDROXIDE PRODUCTS**

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<i>Route of Exposure</i>	<i>Signs and Symptoms</i>
Inhalation	Calcium hydroxide powder may cause irritation of mucous membranes and upper respiratory tract. Paste and liquid preparations cause no symptoms.
Eye Contact	Corrosive. May produce irritation, pain, ulceration of the cornea.
Skin Absorption	Not applicable
Skin Contact	Corrosive. May cause burns, blistering, depending on duration of contact.
Ingestion	Gastric irritant. May cause pain, vomiting, diarrhea, and collapse.
<i>Summary of Chronic Hazards:</i> Narrowing of the esophagus may occur weeks to years after ingestion.	
Carcinogenicity	Not considered a carcinogen.
Reproductive Toxicity, Mutagenicity, Teratogenicity: None known.	
Special Health Effects	Persons with pre-existing skin conditions may be more susceptible to irritation.

***Emergency First Aid Procedures***

Inhalation	Move to fresh air. Seek medical attention if breathing is labored.
Eye contact	Wash with running water for 15+ minutes. Seek immediate medical care.
Ingestion	If swallowed, DO NOT INDUCE VOMITING. Give large quantities of water/ milk, but only if person is conscious. Call physician immediately.
Skin contact	Remove contaminated clothing. Wipe off excess and wash skin with plenty of tepid water. Seek medical attention if irritation persists.

**SECTION VII - PRECAUTIONS FOR SAFE HANDLING & USE**

Handling and Storage Precautions: Keep tightly closed in original container; store in a cool, dry, ventilated area. Protect against physical damage. Isolate from incompatible substances. Paste products: remove applicator tip, add a drop of water to cap and recap syringe immediately after use. Do not leave applicator tip on syringe.

Release or Spill: Wear gloves, safety goggles. Powder spills: wear dust mask; pick up spilled material without dispersing powder into air. Paste and liquid spills: wipe up with paper towels. Wash area of spill with water-saturated paper towels/cloths. Place material and towels in container for disposal.

Waste Disposal Method: Follow government regulations.

Other Precautions: Spills may result in slippery surfaces.

**SECTION VIII - CONTROL MEASURES**

Respiratory Protection: Not necessary under normal conditions of dental practice. If handling large quantities of calcium hydroxide powder, where the TLV may be exceeded, an OSHA-approved dust/mist respirator is recommended.

Ventilation: No special ventilation necessary if level of calcium hydroxide powder is below the TLV.

Protective Gloves: Chemically impervious gloves. Eye Protection: Chemical safety goggles.


Other Protective Clothing or Equipment: Emergency eye wash fountain. Wear lab coat, long sleeves and apron to prevent skin contact. Use rubber dam around tooth to be treated. Mask all surrounding tissue.

Work/Hygienic Practices: Wash hands after use; wash contaminated safety equipment before re-use. Persons regularly using large quantities of the powder form should not wear contact lenses.

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*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.*

## Safety Data Sheet

**Trade Name:** *Multi-Cal™ Calcium Hydroxide Paste*

1.0 Commercial Product Name and Supplier										
1.1	Commercial product name / designation <i>Multi-Cal™ Calcium Hydroxide Paste</i>									
1.2	Application / Use Dental material for use by dental professionals.									
1.2.2	SIC 851 Human health activity									
1.2.3	Use Category 55									
1.3	Manufacturer <b>Pulpdent Corporation</b> 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA Telephone: 1 617 926-6666 / Fax: 1 617 926-6262 Email: <a href="mailto:Pulpdent@pulpdent.com">Pulpdent@pulpdent.com</a>									
1.4	Emergency Telephone Number 1-800-535-5053 (24 Hour / USA)									
1.5	Authorized European Representative Advena Ltd. Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom									
2.0 Hazards Identification										
2.1	Classification									
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP] <table border="1"> <thead> <tr> <th><u>Hazard Class</u></th> <th><u>Hazard Category</u></th> <th><u>Hazard Statement</u></th> </tr> </thead> <tbody> <tr> <td>Skin irritation</td> <td>2</td> <td>H315</td> </tr> <tr> <td>Eye irritation</td> <td>2</td> <td>H319</td> </tr> </tbody> </table>	<u>Hazard Class</u>	<u>Hazard Category</u>	<u>Hazard Statement</u>	Skin irritation	2	H315	Eye irritation	2	H319
<u>Hazard Class</u>	<u>Hazard Category</u>	<u>Hazard Statement</u>								
Skin irritation	2	H315								
Eye irritation	2	H319								
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases) Irritant (Xi), R 36 / 38									
2.2	<b>GHS Label Elements</b>									
	Hazard Pictograms									
										
	Signal Word: <b>WARNING</b>									
	<b>Restricted to use by dental professional only.</b>									
	<b>Hazard Statements</b>									
	H319: Eye irritation. 2. May cause eye irritation.									
	H315: Skin irritation. 2. May cause skin irritation.									
	<b>Precautionary Statements</b>									
	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.									
3.0 Composition										
3.1	Chemical characterization of the preparation Calcium hydroxide suspended in a cellulose/water gel matrix.									

**Safety Data Sheet****Trade Name:** Multi-Cal™ Calcium Hydroxide Paste

3.2	Hazardous ingredients				
	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP).
	1305-62-0	Calcium Hydroxide	39%	Irritant (Xi) R 36 / 38	Skin irritation; 2 Eye irritation; 2
<b>4.0</b>	<b>First Aid Measures</b>				
4.1	Special Instructions	Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty. Calcium hydroxide-based preparations present minimal hazard in the quantities provided. May cause irritation on contact with eyes. Prolonged exposure may cause irritation to mucous membranes, skin, gastrointestinal or respiratory tract.			
4.2	Eye Contact	Keep eyelids apart; 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.			
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.			
	Treatment	Same as First Aid above.			
<b>5.0</b>	<b>Fire Fighting Measures</b>				
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			
<b>6.0</b>	<b>Accidental Release Measures</b>				
6.1	Personal precautions.	Wear gloves, lab coat and chemical splash goggles.			
6.2	Environmental precautions	None			
6.3	Method for clean up	Wipe up/absorb with paper towels. Wash area of spill with water-saturated paper towels/cloths. Place spill and towels in container for disposal.			

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<b>7.0 Handling and Storage</b>		
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 preparation
<b>8.0 Exposure Controls / Personal Protection</b>		
8.1	Exposure limit values	Not available
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..
8.2.1.1	Respiratory protection	Good general ventilation is sufficient to control any airborne vapors.
8.2.1.2	Hand protection	No special requirements other than the usual surgical gloves..
8.2.1.3	Eye protection	No special requirements other than the usual safety glasses..
8.2.1.4	Skin protection	No special requirements. Good personal hygiene, safety practices and wearing a lab coat should protect from unnecessary exposure.
8.2.1.5	Other controls	Emergency eye wash fountain. Wash hands after use.
8.2.2	Environmental exposure controls	Avoid release into environment as may cause pH variation.
<b>9.0 Physical and Chemical Properties</b>		
9.1	Characteristics	
9.1.1	Appearance / Color / Physical state	White paste
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	< 1 mm Hg (Id: A)
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

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9.2.12	Vapor density	Not determined
9.2.13	Evaporation rate	Not determined
<b>10.0</b>	<b>Stability and reactivity</b>	
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.
<b>11.0</b>	<b>Toxicological information</b>	
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.
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
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.
<b>12.0</b>	<b>Ecological Information</b>	
12.1	Ecotoxicity	Not considered detrimental to water or soil. Avoid release into environment as calcium hydroxide may cause pH variation. Follow government regulations.
<b>13.0</b>	<b>Disposal Considerations</b>	
13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.
<b>14.0</b>	<b>Transport Information</b>	
14.1	Restrictions	None. Not regulated.
14.2	UN Number	None
14.3	Technical name	Not applicable
14.4	Packing group	Not applicable
	IATA class	Not applicable

**Safety Data Sheet****Trade Name:** Multi-Cal™ Calcium Hydroxide Paste

<b>15.0 Regulatory Information</b>		
15.1	EU	Class IIa medical device under MDD 93/42/EEC.
15.2	US FDA	Class II medical device
15.3	Health Canada	Class III medical device
<b>16.0 Other information</b>		
16.1	List of relevant R phrases	R 36 / 38: Irritating to eyes and skin.
16.2	Hazard Statements	H319: Eye irritation. 2. May cause eye irritation. H315: Skin irritation. 2. May cause skin irritation.
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.
16.4	Restrictions on use	Calcium hydroxide preparations are to be used only by dental professionals who have been trained in their use.
16.5	Further information	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.
16.6	Sources of key data	National Institute for Occupational Safety (NIOSH) Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency
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, Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.