

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	<u>CALCIUM HYDROXIDE PREPARATIONS</u> <i>Cavity Liner</i> <i>Multi-Cal</i> <i>Pulpdent Paste</i> <i>TempCanal</i> <i>Calcium Hydroxide Powder, USP</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 <i>Pulpdent Corporation</i> 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	Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta
	UK Responsible Person	Advena Limited Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom
	CH Authorized Representative	MedEnvoy Switzerland Gotthardstrasse 28, 6302 Zug, Switzerland

2.0 Hazards Identification			
2.1	Classification		
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<u>Hazard Class</u>	<u>Hazard Category</u>
	Cavity Liner	Skin irritation	2
		Eye irritation	2
	Multi-Cal	Skin irritation	2
		Eye irritation	2
	Pulpdent Paste	Skin irritation	2
		Eye irritation	2
	TempCanal	Skin irritation	2
		Eye irritation	2
	Calcium Hydroxide Powder, USP	Skin irritation	2
		STOT SE	2
		Eye irritation	2
2.1.2	Classification according to WHMIS	D2: Irritant	

Safety Data Sheet**Trade Names:**

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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+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P317: If eye irritation persists, get medical help.

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

CAS Number	Name of the Ingredient	Concentration	Classification per Regulation (EC) No.1272/2008 (CLP).
1305-62-0	Calcium Hydroxide	Cavity Liner: 32%	Skin irritation; 2 Eye irritation; 2
		Multi-Cal: 42 %	Skin irritation; 2 Eye irritation; 2
		Pulpdent Paste: 42%	Skin irritation; 2 Eye irritation; 2
		TempCanal: 39%	Skin irritation; 2 Eye irritation; 2
		Calcium Hydroxide Powder: 100%	Skin irritation; 2 STOT SE; 2 Eye irritation, 2

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,

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		gastrointestinal tract or respiratory tract. Calcium hydroxide powder presents an inhalation hazard if allowed to disperse.
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. 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
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. Remove applicator tip immediately after use and recap. Wear gloves, safety glasses; wash hands after use. Avoid unnecessary exposure. Follow good hygiene practices.
7.2	Storage	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.

Safety Data Sheet**Trade Names:**

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

7.3	Specific uses	Dental preparations
8.0 Exposure Controls / Personal Protection		
8.1	Exposure limit values	<i>Calcium Hydroxide Powder</i> only: PEL / TLV 5 mg/m ³
8.2	Exposure controls	
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	<i>Powdered Calcium Hydroxide</i> : None under normal conditions of dental practice. For large quantities, > PEL/TLV, OSHA-approved dust mask . <i>Paste and liquid preparations</i> : Good general ventilation
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
8.2.1.4	Skin protection	Good personal hygiene and safety practices; wearing a lab coat.
8.2.1.5	Other controls	Emergency eye wash fountain should be close by. Wash hands after use.
8.2.2	Environmental exposure controls	Avoid release into environment; calcium hydroxide may cause pH variation.
9.0 Physical and Chemical Properties		
9.1	Characteristics	
9.1.1	Appearance / Color / Physical state	Cavity Liner: White liquid Multi-Cal: White paste Pulpdent Paste: White paste TempCanal: Thin White paste Calcium Hydroxide Powder USP: White powder
9.1.2	Odor	Mild characteristic
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

Safety Data Sheet**Trade Names:**

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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
11.7	Clinical Experience	Pulpdent calcium hydroxide preparations have been used safely and effectively by dental professionals since 1947 without any reports of adverse events.
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

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15.0 Regulatory Information		
15.1	EU Regulations	Class IIa medical devices under MDD 93/42/EEC.
15.2	US FDA	Class II medical devices
15.3	Health Canada	Class III medical devices
15.4		Calcium Hydroxide Powder USP is not a medical device. It is a USP grade chemical.
16.0 Other information		
16.1	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)
16.2	Precautionary Statements	P280: Wear protective gloves and eye protection P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P317: If eye irritation persists, get medical help. P302+P352: If on skin, wash with plenty of soap and water. P261: Avoid breathing dust. (Calcium hydroxide powder only)
16.3	Restrictions on use	For use by dental professionals only.
16.4	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.
16.5	Sources of key data	National Institute for Occupational Safety (NIOSH) US Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP), Regulation (EU) No 487/2013 and Regulation (EC) No. 1907/2006 (REACH). European Chemicals Agency Guidance on the compilation of safety data sheets Version 4.0 April 2020
16.6	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. 487/2013 (CLP), , (EC) No. 1907/2006 (REACH) and ECHA Version 4.0 April 2020.