

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 CALCIUM 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																																										
1.2.3	Use Category 55																																										
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></th><th><u>Hazard Class</u></th><th><u>Hazard Category</u></th><th><u>Hazard Statement</u></th></tr></thead><tbody><tr><td rowspan="2">Cavity Liner</td><td>Skin irritation</td><td>2</td><td>H315</td></tr><tr><td>Eye irritation</td><td>2</td><td>H319</td></tr><tr><td rowspan="2">Multi-Cal</td><td>Skin irritation</td><td>2</td><td>H315</td></tr><tr><td>Eye irritation</td><td>2</td><td>H319</td></tr><tr><td rowspan="2">Pulpdent Paste</td><td>Skin irritation</td><td>2</td><td>H315</td></tr><tr><td>Eye irritation</td><td>2</td><td>H319</td></tr><tr><td rowspan="2">TempCanal</td><td>Skin irritation</td><td>2</td><td>H315</td></tr><tr><td>Eye irritation</td><td>2</td><td>H319</td></tr><tr><td rowspan="3">Calcium Hydroxide Powder, USP</td><td>Skin irritation</td><td>2</td><td>H315</td></tr><tr><td>STOT SE</td><td>2</td><td>H335</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>	Cavity Liner	Skin irritation	2	H315	Eye irritation	2	H319	Multi-Cal	Skin irritation	2	H315	Eye irritation	2	H319	Pulpdent Paste	Skin irritation	2	H315	Eye irritation	2	H319	TempCanal	Skin irritation	2	H315	Eye irritation	2	H319	Calcium Hydroxide Powder, USP	Skin irritation	2	H315	STOT SE	2	H335	Eye irritation	2	H319
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Safety Data Sheet

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

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

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

Safety Data Sheet

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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 with 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:

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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.
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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	<i>Calcium Hydroxide Powder</i> only: PEL / TLV 5 mg/m ³
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	<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 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	
9.1.1	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

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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

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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
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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, 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.
