

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH)

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

1.0 Commercial Product Name and Supplier		
1.1	Commercial product name / designation	<u>CALCIUM HYDROXIDE PRODUCTS</u> Pulpdent Paste Pulpdent Cavity Liner Pulpdent TempCanal Pulpdent Multi-Cal 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, Importer	
1.3.1	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	International Business Solutions Ltd. 54 Mayfield Ridge, Hatch Warren, Basingstoke, RG22 4RS UK Tel: 07989 407479 / Fax: 01256 350330 Email: scwcgc@globalnet.co.uk
2.0 Hazards Identification		
2.1	Classification	Irritant
2.2	Adverse human health effects	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.
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.

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3.2 Hazardous ingredients

CAS Number	EC No.	Name of the Ingredient	Concentration	Warning symbol, R phrases
1305-62-0	215-137-3	Calcium Hydroxide	Pulp Capping Paste: 42% Cavity Liner: 32% TempCanal: 39% Multi-Cal: 42 % Calcium Hydroxide Powder: 100%	Xi R41, R37

4.0 First Aid Measures

4.1	Special Instructions	Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.
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

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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. 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 and acids.
7.3	Specific uses	Dental preparation
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.

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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	Pulp Capping Paste: White paste Cavity Liner: White liquid TempCanal: White paste Multi-Cal: White paste Calcium Hydroxide Powder USP: White powder
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
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.
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.

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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 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.
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13.0 Disposal Considerations

13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.
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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	Pulpdent Pulp Capping Paste, Cavity Liner, TempCanal, Multi-Cal and Calcium Hydroxide Powder USP are Class IIA Medical Devices under the Medical Devices Directive 93/42/EEC.
15.2	Information on the warning label	
15.2.1	Hazard symbol / Statement	Xi / Irritant
15.2.2	Hazardous ingredient	Calcium hydroxide
15.2.3	Risk phrases	R41: Risk of serious damage to eyes. R37: Irritating to respiratory system (powder only).
15.2.4	Safety phrases	S22: Do not breathe dust (powder only). S26: In case of contact with eyes, flush with running water for 15+ minutes and seek medical advice. S39: Wear eye/face protection
16.0 Other information		
16.1	List of relevant R phrases	R41: Risk of serious damage to eyes. R37: Irritating to respiratory system (powder only).
16.2	Training advice	Calcium hydroxide preparations are to be used only by dental professionals who have been trained in their use.
16.3	Restrictions on use	Calcium hydroxide preparations are to be used only by dental professionals who have been trained in their use.
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) Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law
16.6	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of Regulation (EC) No. 1907/2006 (REACH).