

SAFETY DATA SHEETS

This SDS packet was issued with item:

075898150

N/A

MATERIAL SAFETY DATA SHEET: CALCIUM HYDROXIDE PRODUCTS

IDENTITY:	Trade Name	Code:
	Cavity Liner	PCL
	Multi-Cal	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

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

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

Route of Exposure

Inhalation

Signs and Symptoms

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.

Summary of Chronic Hazards: 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.

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	Multi-Cal™ Calcium Hydroxide Paste	
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	Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta	
2.0 Hazards Identification			
2.1	Classification		
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<u>Hazard Class</u> Skin irritation Eye irritation	<u>Hazard Category</u> 2 2 <u>Hazard Statement</u> H315 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	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.		
	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.		
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
4.0	First Aid Measures				
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.		
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		Wipe up/absorb with paper towels. Wash area of spill with water-saturated paper towels/cloths. Place spill and towels in container for disposal.		

Safety Data Sheet

Trade Name: Multi-Cal™ Calcium Hydroxide Paste

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 preparation
8.0 Exposure Controls / Personal Protection		
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.
9.0 Physical and Chemical Properties		
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

Safety Data Sheet

Trade Name: Multi-Cal™ Calcium Hydroxide Paste

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.
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.
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	Not applicable
14.4	Packing group	Not applicable
	IATA class	Not applicable

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15.0 Regulatory Information		
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
16.0 Other information		
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.