


Safety Data Sheet

Trade Name: **TempCanal**

1.0 Commercial Product Name and Supplier				
1.1	Commercial product name	TempCanal		
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	<p>Pulpdent Corporation 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA</p> <p>Telephone: 1 617 926-6666 Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com</p>		
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)		
1.5	Authorized European Representative	<p>International Business Solutions Ltd. 54 Mayfield Ridge, Hatch Warren, Basingstoke RG22 4RS UK</p> <p>Tel: 07989 407479 / Fax: 01256 350330 Email: s.williams5@btconnect.co.uk</p>		
2.0 Hazards Identification				
2.1	Classification			
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Hazard Class	Hazard Category	Hazard Statement
		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 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.		

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3.2 Hazardous ingredients

CAS Number	Name of the Ingredient	Concentration	Classification according to 67/548/EEC	Classification according to Regulation (EC) No.1278/2008 (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 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.
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 soiled towels in container for disposal.

7.0 Handling and Storage

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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 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. 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	Thin 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

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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.
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	Calcium hydroxide preparation

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14.4 Packing group Not applicable

IATA class Not applicable

15.0 Regulatory Information

15.1 EU Class IIA medical devices 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 Agency16.7 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.