


Safety Data Sheet

Trade Name: **Pulpdent Cavity Liner**

1.0 Commercial Product Name and Supplier												
1.1	Commercial product name / designation	Pulpdent Cavity Liner										
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>Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta</p>										
	UK Responsible Person	<p>Advena Limited Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom</p>										
	CH Authorized Representative	<p>MedEnvoy Switzerland Gotthardstrasse 28, 6302 Zug, Switzerland</p>										
2.0 Hazards Identification												
2.1	Classification											
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<table border="1"> <thead> <tr> <th>Hazard Class</th> <th>Hazard Category</th> <th>Hazard Statement</th> </tr> </thead> <tbody> <tr> <td>Skin irritation</td> <td>2</td> <td>H315</td> </tr> <tr> <td>Eye irritation</td> <td>2</td> <td>H319</td> </tr> </tbody> </table>	Hazard Class	Hazard Category	Hazard Statement	Skin irritation	2	H315	Eye irritation	2	H319	
Hazard Class	Hazard Category	Hazard Statement										
Skin irritation	2	H315										
Eye irritation	2	H319										
2.1.2	Classification according to Directive 67/548/EEC	Irritant (Xi); R 36/38 (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.											
	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.											

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P302+P352: If on skin, wash with plenty of soap and water.

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3.0 Composition											
3.1	Chemical characterization of the preparation Calcium hydroxide suspended in a cellulose/water matrix.										
3.2	Hazardous ingredients										
	<table border="1"> <thead> <tr> <th>CAS Number</th> <th>Name of the Ingredient</th> <th>Concentration</th> <th>Classification per 67/548/EEC</th> <th>Classification per Regulation (EC) No.1272/2008 (CLP).</th> </tr> </thead> <tbody> <tr> <td>1305-62-0</td> <td>Calcium Hydroxide</td> <td>Cavity Liner: 32%</td> <td>Irritant (Xi) R 36 / 38</td> <td>Skin irritation; 2 Eye irritation; 2</td> </tr> </tbody> </table>	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	Cavity Liner: 32%	Irritant (Xi) R 36 / 38	Skin irritation; 2 Eye irritation; 2
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	Cavity Liner: 32%	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. This product presents minimal hazard in the quantity of material provided and typically used. Only with prolonged exposure is it irritating to mucous membranes, eyes, skin, gastrointestinal tract or respiratory tract.										
4.2	Eye Contact Keep eyelids apart; flush with running water for 15+ minutes. Get medical attention for persistent irritation.										
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. Administer artificial respiration as needed; 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, 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: 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 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	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 used for cavity lining
8.0 Exposure Controls / Personal Protection		
8.1	Exposure limit values	Not applicable
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	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 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	White liquid
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

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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.
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.
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
14.5	IATA class	Not applicable

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15.0 Regulatory Information		
15.1	EU Regulations	Class IIa medical device under MDD 93/42/EEC.
15.2	US FDA	Class II medical device
16.0 Other information		
16.1	List of relevant R phrases	R36/38: 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	Cavity Liner is to be sold to and used by dental professionals only.
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.