

Instructions For Use

CE
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PRODUCT DESCRIPTION

TempCanal Enhanced is a root canal treatment paste recommended for routine use between office visits to cleanse canals and prevent flare-ups, and for use in complicated cases when extended calcium hydroxide treatment is indicated.

The paste flows through 27-gauge x 1" (0.4 x 25mm), 2-side-vent, endodontic irrigation needles for direct, one-handed delivery into the root canal. Closed-end needles prevent dispensing beyond the apex. Non-drying formula will not clog 27-gauge needles.

TempCanal Enhanced has a pH>12 and provides the proven benefits of calcium hydroxide for successful root canal therapy. Use routinely as an intracanal dressing and for treatment of periapical lesions and abscesses, internal and external root resorption, traumatic injuries, root fractures and perforations, apexification, and weeping canals.

INSTRUCTIONS FOR USE

1. Prepare and cleanse canal in the usual manner.
2. Attach luer lock dispenser needle securely onto the syringe. (Alternatively, paste can be placed in the canal using a lentulo paste filler.)
3. Insert needle into the canal to the desired depth. The needle is closed end with two side vents.
4. Depress syringe plunger to dispense paste.
5. Fill canal while slowly withdrawing the needle.
6. Seal access opening with your preferred cement.
7. Discard needle and recap syringe immediately after use
8. TempCanal Enhanced is easily removed with file and irrigation.

Precautions: May be irritating to eyes, skin, respiratory system, gastrointestinal tract, or mucous membranes, especially in large quantities or with prolonged exposure. For use by dental professionals only. Wear gloves and safety glasses. Wash hands after use. Avoid unnecessary exposure.

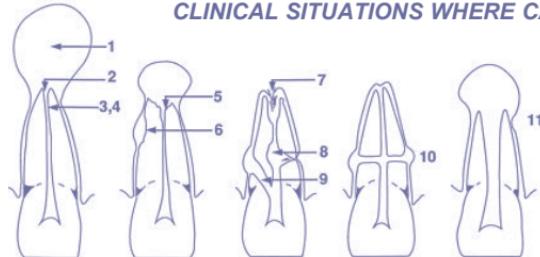


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CLINICAL SITUATIONS WHERE CALCIUM HYDROXIDE CAN BE USED



- 1. exudation control
- 2. large periapical lesions
- 3. antibacterial dressing
- 4. temporary root filling
- 5. apical inflammatory resorption
- 6. inflammatory resorption following trauma

- 7. apical internal resorption
- 8. internal-external root resorption
- 9. perforations
- 10. transverse root fractures
- 11. incompletely developed pulpless teeth

(Heithersay, G.S. Calcium Hydroxide in the Treatment of Pulpless Teeth with Associated Pathology, J. Brit Endo Society, 8[2]: 74-93 July 1975)

Note: Apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient.

For additional information, refer to the following websites:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm>

Español

TEMPCANAL™ ENHANCED

Pasta de Hidróxido de calcio para el tratamiento de los conductos radiculares.

No seca, Radiopaco

DESCRIPCION DEL PRODUCTO

TempCanal Enhanced es un tratamiento en pasta para los conductos radiculares. Es recomendado para un uso de rutina entre las visitas al dentista para limpiar los conductos y prevenir el dolor, y para su uso en casos más complicados cuando se prescribe un tratamiento de hidróxido de calcio prolongado.

La pasta es inyectada a través de una aguja de irrigación de endodoncia de dos orificios: calibre de 27 x 1" (0,4 x 25mm), 2 – Para una aplicación directa con una sola mano en el conducto radicular. Las agujas con fondo obturado "closed-end" evitan la dispersión más allá del ápice. La nueva fórmula no se seca y no tapa las agujas.

TempCanal Enhanced tiene un pH superior a 12 y aporta los beneficios probados para una terapia exitosa de los conductos radiculares. Utilizado sistemáticamente como un apósito interno de los conductos y como tratamiento de lesiones periapicales y abscesos, para una resorción interna y externa, las lesiones traumáticas, las fracturas profundas y perforaciones, la apexificación, y los conductos expandidos.

MODO DE EMPLEO

1. Preparar y limpiar el conducto de manera habitual
2. Colocar una aguja en la jeringa con el seguro "LuerLock". (La pasta puede ser colocada con ayuda de un lénitulo"
3. Inserte la aguja en el conducto a la profundidad deseada. La aguja posee dos ranuras laterales y no tiene salida en su extremidad.
4. Empujar el pistón de la jeringa para sacar la pasta.
5. Rellenar el conducto sacando lentamente la aguja.
6. Sellar la apertura con su cemento habitual.
7. Retirar la aguja y cerrar la jeringa inmediatamente después de su utilización.
8. TempCanal Enhanced puede retirarse fácilmente con una lima e irrigándolo.

Precauciones: Puede ser irritante para los ojos, la piel, las vías respiratorias, la tráquea gastrointestinal, o la mucosa, en particular en grande(s) cantidad(es) o en caso de exposición prolongada.

Debe ser únicamente utilizada por un profesional dental que utilice guantes y lentes de protección. Lavarse las manos después de la utilización. Evitar toda exposición inútil.

Observación: Poner a disposición protecciones (desechables) para uso único de cada paciente. Para mayor información, consulte el siguiente sitio web: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm>

Français

TEMPCANAL™ ENHANCED

Pâte à l'hydroxyde de Calcium pour le traitement canalaire

Ne sèche pas, Radiopaque

DESCRIPTION

TempCanal Enhanced est une pâte de traitement du canal radiculaire. Elle est recommandée dans le cadre d'une utilisation de routine entre les visites au cabinet dentaire pour nettoyer les canaux et prévenir des douleurs, et pour une utilisation dans les cas compliqués lorsqu'un traitement à l'hydroxyde de calcium est indiqué.

La pâte est injectée à travers une aiguille d'irrigation endodontique à deux orifices de calibre : 27 gauge x 1" (0,4 x 25mm), pour une livraison directe à une seule main dans le canal radiculaire. Les aiguilles « Closed-end » empêchent une distribution au-delà de l'apex. La nouvelle formulation ne sèche pas et n'obstrue pas les aiguilles.

TempCanal Enhanced a un pH supérieur à 12 et fournit les bénéfices éprouvés pour un traitement avec succès du canal radiculaire. Utilisé systématiquement comme un pansement intra-canalaire et pour le traitement des lésions péri-apicales et des abcès, la résorption de la racine interne et externe, les lésions traumatiques, les fractures profondes et perforations, l'apexification, et les canaux élargis.

MODE D'EMPLOI

1. Préparer et nettoyer le canal de manière habituelle.
2. Mettre en place l'aiguille sur la seringue avec la sécurité "LuerLock". (La pâte peut être aussi placée au moyen d'un Lentulo).

3. Insérez l'aiguille dans le canal à la profondeur désirée. L'aiguille possède deux fentes latérales et n'a pas de sortie à son extrémité.
4. Pousser sur le piston de la seringue pour faire sortir la pâte.
5. Remplir le canal tout en sortant lentement l'aiguille.
6. Seller l'ouverture avec votre ciment habituel.
7. Jeter l'aiguille et reboucher la seringue immédiatement après utilisation.
8. TempCanal Enhanced peut être facilement retiré avec une lime en irriguant.

Précautions: Peut être irritant pour les yeux, la peau, les voies respiratoires, la trachée gastro-intestinale, ou les muqueuses, en particulier en grande(s) quantité(s) ou par une exposition prolongée.

Doit être uniquement utilisé par les professionnels dentaires en portant des gants et des lunettes protection. Se laver les mains après utilisation. Éviter toute exposition inutile.

Remarque: Mettre en place des protections (jetables) à usage unique pour chaque patient.

Pour plus d'informations, consultez le site web suivant:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm>

Italiano

TEMPCANAL™ ENHANCED

Pasta all'idrossido di calcio per trattamenti canalari provvisori

Non-indurente, radiopaco

DESCRIZIONE DEL PRODOTTO

TempCanal Enhanced è una pasta all'idrossido di calcio per il trattamento canalare. E' raccomandato per l'impiego di routine tra le visite di controllo per pulire i canali e prevenire le infiammazioni e per l'uso in casi complicati in cui è indicato il trattamento esteso con idrossido di calcio.

La pasta scorre attraverso degli aghi d'irrigazione endodontici di calibro 27 (0,4 x 25mm), con due fori laterali, per l'applicazione con una sola mano direttamente nel canale radicolare. Gli aghi chiusi in punta impediscono l'erogazione oltre apice. Formulazione non-indurente per non intasare gli aghi.

TempCanal Enhanced ha un pH >12 e fornisce i comprovati benefici dell'idrossido di calcio per una terapia canalare di successo. Utilizzabile regolarmente come medicazione intracanalare e per il trattamento di lesioni periapicali e ascessi, riassorbimento radicolare interno ed esterno, lesioni traumatiche, fratture radicolari e perforazioni, a specificazioni ed essudazioni periapicali.

ISTRUZIONI PER L'USO

1. Preparare e pulire il canale nel modo consueto.
2. Rimuovere la guaina dall'ago erogatore di TempCanal Enhanced. Fissare l'ago erogatore luer lock in modo sicuro sulla siringa (in alternativa, la pasta può essere collocata nel canale utilizzando un lentulo).
3. Inserire l'ago nel canale fino alla profondità desiderata. L'ago presenta due aperture laterali ed è chiuso sul fondo.
4. Premere lo stantuffo della siringa per erogare la pasta.
5. Riempire il canale ritirando lentamente l'ago.

6. Sigillare l'apertura di accesso con il cemento preferito.
7. Eliminare l'ago e richiudere immediatamente la siringa dopo l'uso.
8. TempCanal Enhanced può essere facilmente rimosso con un file sotto irrigazione.

Precauzioni: può essere irritante per gli occhi, la pelle, il sistema respiratorio, il tratto gastrointestinale o le mucose, soprattutto in grandi quantità o con l'esposizione prolungata. Per l'utilizzo esclusivo di professionisti del settore. Indossare guanti e occhiali protettivi. Lavare le mani dopo l'uso. Evitare l'esposizione non necessaria.

Nota: le siringhe multi-dose devono essere o racchiuse in una copertura protettiva monouso per ogni paziente o pulite e disinfeziate tra un paziente e l'altro, a seconda dei casi. Per ulteriori informazioni, consultare i seguenti siti web:
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm>

Deutsch

TEMPCANAL™ ENHANCED

Temporäre Kalziumhydroxid-Paste für die Kanałbehandlung

Nichtbindend, radiopak

Produktbeschreibung:

TempCanal Enhanced ist eine Paste zur Wurzelkanalbehandlung. Sie wird als Praxisstandard zum reinigen von Kanälen und zum Vorbeugen von Flare-Ups, aber auch für kompliziertere Fälle, wenn eine langfristige Behandlung mit Kalziumhydroxid indiziert ist, empfohlenen.

Die Paste fließt durch die 27-ga x 1st (0,4 x 25 mm), zweiseitig geöffnete, endodontische Irrigationsnadel, was eine direkte Applikation in den Wurzelkanal mit nur einer Hand ermöglicht. Stirnseitig geschlossene Nadeln schützen davor, die Paste über den Apex hinaus zu verteilen. Dank der nicht-trocknenden Formel verstopfen die 27-ga-Nadeln nicht.

TempCanal Enhanced hat einen pH>12 und bietet die wissenschaftlich nachgewiesenen Merkmale von Kalziumhydroxid für eine erfolgreiche Wurzelkanaltherapie. Sie wird als Standardeinlage bei Kanalfüllungen empfohlen Kanalfüllung, Behandlung von Infektionen, periapikale Läsionen und Abszesse, interne und externe Wurzelresorption, traumatische Verletzungen, Wurzelfraktur und -Perforation, Apexifikation und nässende Kanäle.

Gebrauchsanweisung:

1. Aufbereitung und Reinigung des Wurzelkanals auf gewöhnliche Weise.
2. Bringen Sie die Dispensernadel mit Luer-Lock Verschluß fest auf der Spritze an. (Alternativ kann die Paste mit einem Lentulo-Pastenstopfer eingebracht werden.)
3. Führen Sie die Nadel bis zur gewünschten Tiefe in den Kanal ein. Die Nadel ist stirmseitig geschlossen und seitlich zwei Öffnungen.
4. Drücken Sie mit dem Spritzen-Kolben die Paste heraus.
5. Füllen Sie den Kanal durch langsames Bewegen der Nadel.
6. Versiegeln Sie die Zugangsöffnung mit Ihrem bevorzugten Zement.
7. Entsorgen Sie die Nadel und verschließen Sie die Spritze sofort nach dem Gebrauch.
8. TempCanal Enhanced lässt sich mit Feile und Irrigation leicht entfernen.

Sicherheitsmaßnahmen: Kann in hohen Mengen oder bei häufiger Anwendung Augen, Haut, Atemorgane, Magen-Darm-Trakt und Schleimhäute reizen. Nur für den zahnärztlichen Gebrauch. Bitte tragen Sie Handschuhe und Schutzbrillen. Waschen Sie nach der Anwendung Ihre Hände. Vermeiden Sie unnötigen Kontakt mit der Paste.

Bemerkung:

Verwenden Sie für den Dispenser bitte stets Einweg-Schutzhüllen vor dem Einsatz am Patienten. Weitere Informationen finden Sie auf der folgenden Website:

http://www.fda.gov/MedicalDevices/Products_andMedicalProcedures/DentalProducts/ucm404472.htm

Nederlands

TEMPCANAL™ ENHANCED

PRODUCTBESCHRIJVING

TempCanal Enhanced is een wortelkanaal pasta. Voor de routine kanaalbehandeling tussen praktijkbezoeken om het wortelkanaal schoon te maken en ter voorkoming van "flare-ups", en voor gebruik in complexe gevallen wanneer uitgebreide calciumhydroxide therapie is vereist.

De pasta gaat door een 27-gauge x 1"(0.4 x 25mm) endodontische irrigatiernaald met een dubbele laterale opening voor een directe aanbrenging in het wortelkanaal. Door de laterale opening is er minder kans op extrusie van natriumhypochloriet in het apicale weefsel. De niet drogende pasta zal de 27-gauge naald niet verstoppen.

TempCanal Enhanced heeft een pH waarde van >12 en biedt de bewezen voordelen van werking van calciumhydroxide voor een succesvolle wortelkanaalbehandeling. Voor een regelmatig gebruik als intrakanaal medicament en voor de behandeling van periapicale laesies en abcessen, interne en externe wortelresorptie, traumatische verwondingen, wortelfracturen en perforaties, apexfixatie en bloedend kanaal.

INSTRUCTIES VOOR GEBRUIK

1. Prepareer en reinig het kanaal op een conventionele wijze
2. Draai de naald volledig op de spuit
3. Steek de naald in het kanaal naar de gewenste lengte. Het is een gesloten naald met twee laterale openingen
4. Om te beginnen met sputten, de schroefplunger langzaam draaien
5. Vul het kanaal door de plunger te draaien terwijl u langzaam de naald terugtrekt.
6. Sluit de opening af met het door u gewenste cement
7. Verwijder naald en recap de spuit direct na gebruik
8. TempCanal Enhanced is gemakkelijk te verwijderen met vlijf en irrigatie.

Voorzorgsmaatregelen: irriterend voor de ogen, huid, luchtwegen, maag-darmkanaal of slijmvliezen, vooral in grote hoeveelheden of langdurige blootstelling. Voor gebruik door Dental Professionals. Draag handschoenen en een veiligheidssbril. Handen wassen na gebruik. Vermijd onnodige blootstelling.

Portuguese

TEMPCANAL™ ENHANCED

Pasta de hidróxido de cálcio para o tratamento provisório de canal

Não endurece, Radiopaco

Descrição do Produto

TempCanal Enhanced é uma pasta para tratamento de canal radicular. Recomenda-se para uso corrente entre consultas para limpar os canais e prevenir recidivas, bem como para usar em casos complicados quando esteja indicado prolongar o tratamento com hidróxido de cálcio.

A pasta flui através da agulha de irrigação endodôntica de calibre 27 x 1 "(0,4 x 25 mm), de ventilação lateral dupla, para aplicação direta no canal radicular, apenas com uma só mão. As agulhas com a terminação fechada evitam dispensar material para além do Apex. Fórmula que não endurece e que não vai entupir agulhas de calibre 27".

TempCanal Enhanced tem um pH> 12 e proporciona os comprovados benefícios do hidróxido de cálcio para um tratamento de canal bem-sucedido. Usar rotineiramente para o tratamento intracanal, para lesões peri-apicais e abscessos, reabsorção radicular interna e externa, lesões traumáticas, fractura de raízes e perfurações, apexificação, e canais com exsudação.

INSTRUÇÕES DE UTILIZAÇÃO

1. Preparar e limpar o canal da forma habitual.
2. Conectar a agulha dispensadora luer lock firmemente na seringa. (Alternativamente, a pasta pode colocar-se no canal usando uma broca lental de enchimento.)
3. Inserir a agulha no canal na profundidade desejada. A agulha tem a extremidade fechada com duas aberturas laterais.
4. Comprimir o êmbolo da seringa para dispensar a pasta.
5. Preencher o canal enquanto lentamente retira a agulha.
6. Selar a abertura de acesso com o cimento da sua preferência.
7. Descartar a seringa imediatamente após utilização.
8. TempCanal Enhanced remove-se facilmente com uma lima e irrigação.

Cuidados: Pode ser irritante para os olhos, pele, sistema respiratório, tracto gastro intestinal, ou membranas mucosas, especialmente em grandes quantidades ou com exposição prolongada.

Para ser usado exclusivamente por profissionais de saúde dentária. Utilizar luvas e óculos de protecção. Lavar as mãos depois de cada utilização. Evitar contacto quando não for necessário.

Nota: Usar mangas de protecção descartáveis/cobrir os múltiplos dispensadores dentários antes de utilizar em cada paciente. Para informação adicional, consultar os seguintes websites:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm>

1.0 Commercial Product Name and Supplier

1.1	Commercial product name / designation	TempCanal Enhanced
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 Ltd. Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom

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

2.1.3 Classification according to WHMIS

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+P338: If IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 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 matrix.

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	25%	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.			
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. Dental preparation used for cavity lining
7.3	Specific uses	

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	Thin white paste
9.1.2	Odor	Mild, characteristic
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	1.470 g/ml
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.
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
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
15.3	Health Canada	Class III 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+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 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. TempCanal Enhanced is to be sold to and used by dental professionals only.
16.4	Restrictions on 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.



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