Pulpdent® Paste

For Vital Pulp Therapy and Root Canal Therapy

Pulpdent Paste is the original premixed calcium hydroxide methylcellulose pulpal dressing for vital pulp therapy and root canal therapy. It is radiopaque and requires no mixing.

Pulpdent Paste has a pH >12. It is applied directly on the vital pulp in all pulp capping, pulpotomy and curettage procedures. Pulpdent Paste stimulates the pulp to form a new dentin bridge which is visible clinically after approximately 2–3 months and which re-encloses the pulp in its own natural protective chamber. A hard base must be placed over the dressing prior to the placement of the final restoration.

Pulpdent Paste is a clinically proven dressing for the stimulation of hard tissue formation and root repair in the non-vital root canal. Its uses include temporary canal filling, apexification and other hard tissue formation, and the treatment of traumatic injuries, root resorption, apical cysts and abscesses, periapical lesions, exudation, perforation and root fractures. Pulpdent Paste discourages traumatic external resorption in the reimplanted avulsed tooth and is ideal as a dressing for weeping canals and after the removal of serous exudate and pus.

INGREDIENTS: Calcium Hydroxide, Aqueous Methylcellulose, Barium Sulfate

PRODUCT DESCRIPTION

Pulpdent Paste is the original premixed calcium hydroxide methylcellulose pulpal dressing for vital pulp therapy and root canal therapy.

INDICATIONS

Direct Pulp Capping, Dentin Bridge Formation, Root Canal Therapy, Apexification

CONTRAINDICATIONS

Not for use as a hard-setting base or hard-setting root canal filling material

INSTRUCTIONS FOR USE

For Vital Pulp Therapy

1. Place an 18 gauge needle securely on the syringe with a twist. The needle can be bent to facilitate access to cavity. Alternatively, dispense a small amount of paste on a pad and place into cavity with an appropriate instrument.
2. **For pulpotomy**, place 2–3mm of Pulpdent Paste onto pulp. **For pulp capping**, place 1–2mm of Pulpdent Paste at the exposure site.
3. Dry with stream of air to create a “crust”.
4. Gently tamp Pulpdent Paste with a pledget of cotton to assure contact with the pulp. Again dry with stream of air.
5. Flow hard setting cement over the Pulpdent Paste for compressive strength. Place final restoration.

For Root Canal Therapy

1. Fill root canal with Pulpdent Paste using an 18 gauge Pulpdent Paste needle, the Pulpdent Pressure Syringe, a lentulo spiral or a blunt paper point.
2. Cover with a pledget of cotton and a temporary filling material.
3. Pulpdent Paste can be removed by minimal filing and normal irrigating agents and replaced as necessary until the desired results have been achieved. The root canal can then be obturated by an appropriate method.

NOTE: Use a new applicator tip for each patient. To extend shelf life of Pulpdent Paste, place a drop of water in the cap and recap syringe promptly after each use.

The Original Pre-Mixed Calcium Hydroxide Dressing

Pulpdent® Paste

CE 0459

STORAGE AND HANDLING

- Store tightly sealed in original container at cool room temperature. Avoid direct light, extremes of temperature, contamination and sources of ignition.
- Shelf life of unopened product: 2 years from date of manufacture.
- Re-cap immediately after use.

CAUTION

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

REPORTING OF SERIOUS INCIDENTS

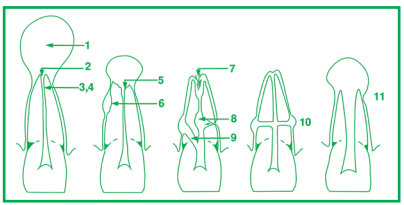
Any serious incidents involving the device should be reported to the manufacturer and the Competent Authority of the Member State in which the incident occurred, or other appropriate regulatory body. Reports of serious incidents should be sent to:

Pulpdent Corporation
80 Oakland Street, Watertown, MA 02472 USA
Tel: 617-926-6666 / Fax: 617-926-6262
email: pulpdent@pulpdent.com

Note: Apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient. For additional information, refer to: https://www.fda.gov/medical-devices/dental-devices/multiple-use-dental-dispenser-devices

Note: Refer to the Safety Data Sheet for a list of materials present in this product.

CLINICAL SITUATIONS WHERE PULPDENT PASTE 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. root 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)

DE:

PULPDENT®

Pulpdent® Paste

Für Vitalpulptherapie und Wurzelkanaltherapie

Produktbeschreibung

Pulpdent Paste ist ein original vorgemischter Pulpaverband aus Calciumhydroxid-Methylcellulose für die Vitalpulpatherapie und Wurzelkanaltherapie.

Indikationen

Direkte Pulpaüberkappung, Dentinbrückenbildung, Wurzelkanaltherapie, Apexifikation

Kontraindikationen

Nicht indiziert als vollständig aushärtende Basis oder vollständig aushärtendes Wurzelkanalfüllmaterial

Gebrauchsanweisung

Vitalpulpatherapie

1. Entfernen Sie den Plastikverschluss. Setzen Sie eine 18-Gauge-Nadel mit einer Drehung sicher auf die Spritze. Um den Zugang zur Kavität zu erleichtern, können Sie die Nadel biegen. Alternativ können Sie eine kleine Menge Paste auf ein Pad geben und mit einem geeigneten Instrument in die Kavität einbringen.
2. **Pulpotomie** empfiehlt sich die Platzierung von 2-3 mm Pulpdent Paste direkt auf die Pulpa. **Zur Pulpaüberkappung** genügt bereits eine Schicht von 1-2mm Pulpdent Paste auf die geöffnete Pulpa.
3. Mit einem Luftstrohm trocknen, damit eine "Kruste" entsteht.
4. Pulpdent Paste mit einem Wattebausch sanft andrücken, um den Kontakt mit dem Zellstoff sicherzustellen. Erneut mit Luftstrom trocknen.
5. Lassen Sie hart abbindenden Zement über die Pulpdent Paste fließen, um die Druckfestigkeit zu erhöhen. Setzen Sie die endgültige Restauration ein.

Wurzelbehandlung

1. Füllen Sie den Wurzelkanal mit Pulpdent Paste unter der Verwendung der mitgelieferten Nadeln, einer Pulpdent Pressure Spritze, einer Lentulo Nadel oder mithilfe einer Papierspitze.
2. Pulpdent Paste kann durch minimales Feilen und normale Spülmittel entfernt und bei Bedarf ersetzt werden, bis das gewünschte Ergebnis erreicht ist. Der Wurzelkanal kann dann mit einer geeigneten Methode obturiert werden.
3. Pulpdent Paste kann durch minimales Feilen und normale Spülmittel entfernt und bei Bedarf ersetzt werden, bis das gewünschte Ergebnis erreicht ist. Der Wurzelkanal kann dann mit einer geeigneten Methode obturiert werden.

Bemerkung: Verwenden Sie für jeden Patienten eine neue Applikatorspitze. Um die Haltbarkeit von Pulpdent Paste zu verlängern, geben Sie einen Tropfen Wasser in die Kappe und füllen Sie die Spritze nach jedem Gebrauch sofort wieder auf.

Lagerung und Handhabung

- Gut verschlossen in der Original-Verpackung lagern bei kühler Raumtemperatur.
- Direktes Licht und extreme Temperaturschwankungen vermeiden. Vor Kontamination und Zündquellen schützen.
- Haltbarkeit bei ungeöffneter Packung: 2 Jahre ab Herstellungsdatum.
- Nach Gebrauch sofort verschließen.

Warnhinweis

Kann die Augen, die Haut, die Atemwege, den Magen-Darm-Trakt oder die Schleimhäute reizen, insbesondere in großen Mengen und/oder bei längerer Exposition. Nur für zahnärztliches Fachpersonal bestimmt. Handschuhe und Schutzbrille tragen; nach Gebrauch Hände waschen. Vermeiden Sie unnötige Exposition.

Meldung von schwerwiegenden Vorkommnissen

Alle schwerwiegenden Vorkommnissen im Zusammenhang mit dem Produkt sollten dem Hersteller und der zuständigen Behörde des Mitgliedstaats, in dem das Vorkommnis aufgetreten ist, oder einer anderen zuständigen Aufsichtsbehörde gemeldet werden.

Berichte über schwerwiegende Vorkommnisse sind zu senden an:

Pulpdent Corporation
80 Oakland Street, Watertown, MA 02472 USA
Tel: 617-926-6666 / Fax: 617-926-6262
E-Mail: pulpdent@pulpdent.com

Bemerkung : Bringen Sie vor der Verwendung bei jedem Patienten Einweg-Barriereschutzhüllen/-wicklungen über den zahnärztlichen Mehrfach-Dispenser an. Weitere Informationen finden Sie unter https://www.fda. gov/medical-devices/dental-devices/multiple-use-den- tal-dispenser-devices

Hinweis : Eine Liste der in diesem Produkt enthaltenen Materialien finden Sie im Sicherheitsdatenblatt.

Pulpdent Paste wird für alle in der Veröffentlichung von G.S. HEITHERSAY angeführten klinischen Situationen verwendet (siehe nebenstehende Skizze).

1) Exsudationskontrolle 2) Große periapikale Läsionen 3) Antibakterielle Wurzelkanaleinlage 4) Temporäre Wurzelkanalfüllung 5) Entzündliche apikale Resorptionen 6) Entzündliche Wurzelresorptionen nach Traumen 7) Interne Granulome 8) Interne – externe Wurzelresorptionen 9) Perforationen 10) Wurzelquerfrakturen 11) Devitale Zähne mit nicht abgeschlossenem Wurzelwachstum (Heithersay, G.S., Calcium Hydroxide in the Treatment of Pulpless Teeth with Associated Pathology, J. Brit Endo Society, 8[2]: 74-93 July 1975)

FR:

***PULPDENT*®**

Pulpdent® Paste

Pour le traitement du tissu pulpaire vivant et le traitement canalaire

Description du Produit

Pulpdent Paste est le pansement pulpaire original et prémélangé à base d'hydroxyde de calcium et de méthylcellulose pour le traitement du tissu pulpaire vivant et le traitement canalaire.

Indications

Coiffage pulpaire direct, formation de pont dentinaire, traitement canalaire, apexification.

Contre-indications

Ne pas utiliser comme base à prise dure ou matériau d'obturation canalaire à prise dure.

Instructions d'Utilisation

Pour la Conservation de la Vitalité Pulpaire :

1. Placer une aiguille de calibre 18 solidement sur la seringue. L'aiguille peut être pliée pour faciliter l'accès à la cavité. Alternativement, déposer une petite quantité de pâte sur un tampon et la placer dans la cavité avec un instrument approprié.
2. Dans les cas de **pulpotomie**, placer 2 – 3mm d'épaisseur de Pulpdent Paste directement sur la pulpe exposée. Dans les cas de **coiffage pulpaire**, placer 1 - 2mm d'épaisseur de Pulpdent Paste directement sur la pulpe exposée.
3. Sécher avec un jet d'air jusqu'à ce qu'une « croûte » apparaisse.
4. Tamponner légèrement la pâte avec une boulette de coton afin de s'assurer que Pulpdent Paste est en contact avec la pulpe. Sécher à nouveau avec un jet d'air.
5. Placer une fine couche de ciment dur sur Pulpdent Paste pour assurer une résistance à la compression. Mettre en place le matériau de restauration.

Pour le Traitement Canalaire :

1. Remplir le canal radiculaire avec Pulpdent Paste à l'aide d'une aiguille Pulpdent Paste de calibre 18, de la seringue à pression Pulpdent, d'un lentulo ou d'une pointe en papier émoussée.
2. Couvrir d'une compresse de coton et d'un matériau de remplissage temporaire.
3. Pulpdent Paste peut être enlevé par un limage minimal et des agents d'irrigation normaux et remplacé si nécessaire jusqu'à ce que les résultats souhaités aient été obtenus. Le canal radiculaire peut alors être obturé par une méthode appropriée.

Remarque

Utiliser un nouvel embout applicateur pour chaque patient. Pour prolonger la durée de conservation de Pulpdent Paste, placer une goutte d'eau dans le capuchon et reboucher la seringue rapidement après chaque utilisation.

Stockage et Manipulation

- Conserver hermétiquement clos dans le contenant original à température ambiante fraîche. Eviter la lumière directe, les températures extrêmes, la contamination et les sources d'ignition.
- Validité du produit non ouvert : 2 ans à partir de la date de fabrication.
- Reboucher immédiatement après l'usage.

Mise en garde

Peut être irritant pour les yeux, la peau, le système respiratoire, le tractus gastro-intestinal ou les muqueuses, en particulier en grande quantité et/ou en cas d'exposition prolongée. À l'usage des professionnels dentaires seulement. Porter des gants et des lunettes de sécurité ; se laver les mains après utilisation. Éviter les expositions inutiles.

Notification des incidents graves

Tout incident grave impliquant le dispositif doit être notifié au fabricant et à l'autorité compétente de l'État membre dans lequel l'incident s'est produit, ou à tout autre organisme de réglementation approprié.

Les rapports d'incidents graves doivent être envoyés à :

Société Pulpdent

80 Oakland Street, Watertown, MA 02472 États-Unis

Tél. : 617-926-6666 / Fax : 617-926-6262

courriel : pulpdent@pulpdent.com

d'informations, veuillez consulter le site web https://www.fda.gov/medical-devices/dental-devices/ multiple-use-dental-dispenser-devices

Remarque : Veuillez vous reporter à la fiche de données de sécurité pour une liste des matériaux présents dans ce produit.

Cas cliniques ou la pâte d'hydroxyde de calcium Pulpdent Paste peut être utilisée:

1. Contrôle de l'exsudation. 2. Grande lésions péri-apicales. 3. Pansements anti-bactériens. 4. Obturations endocanalaires provisoires. 5. Résorbtion radiculaire externe d'origine infectieuse. 6. Résorbtion radiculaire interne. 7. Résorbtion radiculaire externe d'origine inflammatoire. 8. Résorbtion radiculaire interne-externe. 9. Traitement des perforations. 10. Fractures transversales des racines. 11. Apexification, formation d'autres tissus durs. (Heithersay, G.S., Calcium Hydroxide in the Treatment of Pulpless Teeth with Associated Pathology, J. Brit Endo Society, 8[2]: 74-93 July 1975)

ES:

Pulpdent® Paste

Para terapia pulpar vital y terapia de conducto radicular

Descripción del producto

Pulpdent Paste es el apósito pulpar original de metilcelulosa de hidróxido de calcio premezclado para la terapia pulpar vital y la terapia del conducto radicular.

Indicaciones

Recubrimiento pulpar directo, formación de puentes de dentina, tratamiento del conducto radicular, apexificación.

Contraindicaciones

No debe usarse como base de fraguado rigido o material de relleno de conducto radicular de fraguado rigido.

Instrucciones de uso

Para la Terapia de la Pulpa Vital

1. Coloque una aguja de calibre 18 de forma segura sobre la jeringa con un movimiento de giro. Doble la aguja para facilitar el acceso a la cavidad. Alternativamente, aplique una pequeña cantidad de pasta en un pad desechable y colóquela en la cavidad con un instrumento apropiado.
2. Para pulpotomía, coloque 2 o 3 mm de Pulpdent Paste sobre la pulpa. Para cubrir la pulpa, coloque 1-2 mm de Pulpdent Paste sobre la porción expuesta.
3. Secar con un chorro de aire para crear una “costra”.
4. Empuje suavemente la pasta colocada con una torundita de algodón a fin de asegurar que ésta entre en contacto con la pulpa. Seque nuevamente con aire.
5. Mezcle una porción pequeña de cemento de fraguado rigito sobre la pasta Pulpdent. Coloque la restauración final.

Para preparación de la raíz

1. Obture el conducto radicular con Pulpdent Paste, utilizando una aguja de Pasta Pulpdent de calibre 18, la Jeringa de Presión Pulpdent, un lentulo o una punta de papel.
2. Cubra con una torunda de algodón y un material de obturación temporal
3. La pasta Pulpdent podrá ser retirada con agentes de irrigación o de obturación y reposicionada conforme fuera necesario, hasta que se hayan obtenido los resultados deseados. El conducto radicular puede entonces ser obturado con el método adecuado.

Nota : Utilice una nueva punta aplicadora para cada paciente. Para prolongar la vida útil de Pulpdent Paste, coloque una gota de agua en la tapa y vuelva a tapar la jeringa inmediatamente después de cada uso.

Almacenamiento y Manipulación

- Almacene bien cerrado en el contenedor original a temperatura ambiente. Evite la luz directa, los extremos de temperatura, contaminación y fuentes de ignición.
- Vida útil del producto sin abrir: 2 años a partir de la fecha de fabricación.
- Volver a tapar inmediatamente después de su uso.

Precaución

Puede causar irritación en los ojos, la piel, el sistema respiratorio, el tracto gastrointestinal o las membranas mucosas, especialmente en grandes cantidades y / o con exposición prolongada. Para uso exclusivo de profesionales dentales. Use guantes, gafas de seguridad; lavarse las manos después de su uso. Evite la exposición innecesaria.

Reporte de incidentes graves

Cualquier incidente grave relacionado con el dispositivo debe notificarse al fabricante y a la autoridad competente del Estado miembro en el que ocurrió el incidente, u otro organismo regulador apropiado.

Los informes de incidentes graves deben enviarse a:

Corporación Pulpdent

80 Oakland Street, Watertown, MA 02472 EE. UU.

Tel: 617-926-6666 / Fax: 617-926-6262

correo electrónico: pulpdent@pulpdent.com

Nota : Utilice envolturas de barrera desechables sobre los dispensadores dentales de uso múltiple antes de usarlos con cada paciente. Para obtener información adicional, consulte: https://www.fda.gov/ medical-devices/dental-devices/multiple-use-dental-dispenser-devices.

Nota : Consulte la hoja de datos de seguridad para obtener una lista de los materiales presentes en este producto.
Situaciones Clínicas Donde Se Puede Utilizar La Pasta Pulpdent, Pasta De Hidróxido De Calico
1) Control de exudación. 2) Lesiones periapicales grandes. 3) Cubierta antibacteriana. 4) Obturación radicular temporaria. 5) Reabsorción apical inflamatoria. 6) Reabsorción inflamatoria post-traumática. 7) Reabsorción apical interna. 8) Reabsorción radicular externo-interna 9) Perforaciones 10) Fracturas radiculares transversales . 11) Dientes depulpados con desarrollo incompleto
(Heithersay, G.S. "El Hidróxido de calcio en el tratamiento de dientes depulpados con patología asociada" J. British Endodontic Society 8(2) 74-93 Julio 1975)

IT:

Pulpdent® Paste

Per la terapia della polpa vitale e il trattamento dei canali radicolari

Descrizione del prodotto

Pulpdent Paste è l'originale medicazione pulpare premiscelata con idrossido di calcio e metilcellulosa per la terapia della polpa vitale e il trattamento dei canali radicolari

Indicazioni

Incappucciamento diretto della polpa, formazione di ponti dentinali, trattamento dei canali radicolari, apicificazione.

Controindicazioni

Non indicato per l'utilizzo come base a presa dura o materiale di riempimento dei canali radicolari a presa dura.
Istruzioni per l'uso

Per la terapia della polpa vitale

1. Posizionare saldamente un ago da 18 gauge sulla siringa. L'ago può essere piegato per facilitare l'accesso alla cavità. In alternativa, dispensare una piccola quantità di pasta su un blocchetto d'impasto e inserirla nella cavità con uno strumento appropriato.
2. In caso di pulpotomia, distribuire uno strato di Pulpdent Paste di circa 2-3 mm di spessore direttamente sulla polpa. Per incappucciare la polpa, stendere il prodotto in uno strato di 1-2 mm sulla parte esposta.
3. Asciugare con un getto d'aria per creare una "crosta".
4. Tamponare delicatamente il prodotto con del cotone, così da assicurare il contatto con la polpa. Asciugare nuovamente con un getto d'aria.
5. Ricoprire Pulpdent Paste con un cemento a presa dura per creare resistenza alla compressione. Eseguire il restauro definitivo.

Per il trattamento dei canali radicolari

1. Riempire il canale radicolare con Pulpdent Paste utilizzando un ago Pulpdent Paste da 18 gauge, la siringa a pressione Pulpdent, un lentulo o un cono di carta smussato.
2. Chiudere il canale con un tampone di cotone e con del materiale per otturazione provvisoria.
3. Pulpdent Paste può essere rimossa con una leggera limatura e con normali agenti irriganti e può essere riapplicata quante volte si ritiene necessario, fino al raggiungimento dei risultati prefissati. Il canale radicolare può quindi essere otturato con un metodo appropriato.

Nota: Utilizzare una nuova punta dell'applicatore per ogni paziente. Per prolungare la durata di conservazione di Pulpdent Paste, mettere una goccia d'acqua nel tappo e richiudere la siringa subito dopo ogni utilizzo.

Conservazione e gestione

- Conservare nel contenitore originale ben sigillato a temperatura ambiente fresca. Evitare la luce diretta, temperature estreme, contaminazione e fonti di ignizione.
- Periodo di validità del prodotto non aperto: 2 anni dalla data di produzione.
- Richiudere immediatamente dopo l'uso.

Attenzione

Il materiale può causare irritazione a contatto con gli occhi, la pelle, il sistema respiratorio, il tratto gastrointestinale o le mucose, specialmente in grandi quantità e/o con esposizione prolungata. Ad uso esclusivo dei professionisti del settore odontoiatrico. Indossare guanti, occhiali di sicurezza; lavarsi le mani dopo l'uso. Evita l'esposizione non necessaria.

Segnalazione di incidenti gravi

Qualsiasi incidente grave che coinvolga il dispositivo deve essere segnalato al produttore e all'autorità competente dello Stato membro in cui si è verificato l'incidente, o altro organismo di regolamentazione appropriato. Le segnalazioni di incidenti gravi devono essere inviate a:

Pulpdent Corporation
80 Oakland Street, Watertown, MA 02472 USA
Tel: 617-926-6666 / Fax: 617-926-6262
e-mail: pulpdent@pulpdent.com

Nota: Applicare delle protezioni monouso sulla siringa e cambiare il puntale dopo ogni paziente

Per ulteriori informazioni vedere : https://www.fda.gov/medical-devices/dental-devices/multiple-use-dental-dispenser-devices

Nota: Consultare la scheda di sicurezza per un elenco dei materiali presenti in questo prodotto.

Situazioni cliniche in cui è possibile utilizzare Pulpdent Paste:

1. controllo essudazione 2. ampie lesioni periapicali 3. medicazione antibatterica 4. otturazione provvisoria radicolare 5. riassorbimento infiammatorio apicale 6. riassorbimento infiammatorio in seguito a trauma 7. riassorbimento apicale interno 8. riassorbimento radicolare interno-esterno 9. perforazioni radicolari 10. fratture radicolari trasversali 11. denti non completamente sviluppati e senza polpa

(Heithersay, G. S., "L'idrossido di calcio nel trattamento dei denti senza polpa con patologia associata"
J. Brit Endo Society, 8 (2):74-93 July 1975)

SAFETY DATA SHEET

Trade Name: Pulpdent Paste

1.0 Commercial Product Name and Supplier

1.1	Commercial product name	Pulpdent 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 Ltd. Pure Offices, Plato Close Warwick CV34 6WE UK
	UK Responsible Person	Advena Limited 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** Irritant (Xi), R 36 / 38

(See SECTION 16 for full text of risk phrases)

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.

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 with 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 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 (>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	Appearance / Color	
9.1.1	Color	White paste
9.1.2	Odor	Odorless
9.2	Important health, safety and environmental information	
		pH > 12
9.2.1	pH	Decomposes
9.2.2	Boiling point	Not combustible
9.2.3	Flash point	Not combustible
9.2.4	Flammability (solid, gas)	Not applicable
9.2.5	Explosive properties	Not determined
9.2.6	Oxidizing properties	< 1 mm Hg (Id: A)
9.2.7	Vapor pressure	Not determined
9.2.8	Specific gravity	Slight
9.2.9	Solubility in water	
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 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
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	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, 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.

Leibetseder Dentalwarenhandel GmbH
Hans-Zach-Straße 2
4210 Gallneukirchen
Austria

Plandent OY
Asentajankatu 6 B
00880 Helsinki
Finland

OPSYSE
18 Allée du Fenouil
ZA Saint Louis
84250 Le Thor
France

KinderDent GmbH
Gutenbergstraße 7
28844 Weyhe
Germany

Ortho Organizers GmbH
Lauenbühlstraße 59
88161 Lindenberg im Allgäu
Germany

Bohumila Sieglová
Kolmá 303
25203 Řitka
Czech Republic

Hu-Fa Dental a.s.
Moravní 909
765 02 Otrokovice
Czech Republic

Dental Medical Ireland
Kellystown House
Kellystown Lane, Leixlip
Co. Kildare, W23 VF9P
Ireland

Ravelli S.p.A.
Via Darwin 32-34
20019 Settimo Milanese
Italy

Virdental, UAB
Artojų g. 52B, Garliavos Apylinkių seniūnija
Teleičių kaimas
53273, Kauno Rajonas
Lithuania

Cenger Scandinavia A/S
Urlevvej 6 B
8783 Hornsyld
Denmark

Dansk Nordenta A/S
Nydamsvej 8
8362 Hørning
Denmark

Hofmeester Dental B.V.
Andries Copierhof 2
3059 LM Rotterdam
Netherlands

Equadent Sp z o.o.
ul. Pck 12
62-500 Konin
Poland

GAMA Dental AB
Västbergavägen 24
126 30 Hägersten
Sweden

Lifco Dental AB
Verkmästaregatan 1
745 39 Enköping
Sweden

PULPDENT Corporation

80 Oakland Street • Watertown, MA 02472 • U.S.A.
(617) 926-6666 or (800) 343-4342 • Fax (617) 926-6262
www.pulpdent.com • pulpdent@pulpdent.com

XP-PSYK-IN-10
REV: 11/2021