Pulpdent Corporation

Revision Date: June 14, 2022

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 Limited
Tower Business Centre, 2nd Floor,
Tower Street,
Swatar, BKR 4013 Malta
UK Responsible Person | Advena Limited
Pure Offices, Plato Close
Warwick, CV34 6WE United Kingdom
CH Authorized Representative | MedEnvoy Switzerland
Gotthardstrasse 28, 6302 Zug, Switzerland

2.0 Hazards Identification

2.1 Classification

2.1.1 Classification according to Regulation (EC) No. 1272/2008 [CLP]

<table>
<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>

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

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

<table>
<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>39%</td>
<td>Irritant (Xi); R 36 / 38</td>
<td>Skin irritation; 2</td>
</tr>
</tbody>
</table>

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 spilled material and absorbent 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

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
Good personal hygiene and safety practices; wearing a lab coat.

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

9.2.12 Vapor density
Not determined

9.2.13 Evaporation rate
Not determined

10.0 Stability and reactivity
## 10.0 Handling and Storage

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 with no reports of adverse events.

## 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
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)

### 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.