1.0 Commercial Product Name and Supplier

1.1 Commercial product name / designation

FORENDO™ 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

United Kingdom

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>
<tr>
<td>STOT SE Respiratory tract irritant</td>
<td>3</td>
<td>H335</td>
</tr>
<tr>
<td>Acute toxicity (oral)</td>
<td>4</td>
<td>H302</td>
</tr>
<tr>
<td>Acute toxicity (dermal)</td>
<td>4</td>
<td>H312</td>
</tr>
<tr>
<td>Harmful if inhaled</td>
<td>4</td>
<td>H332</td>
</tr>
</tbody>
</table>

2.1.2 Classification according to Directive 67/548/EEC

Xi (Irritant) ; R41, R20/21/22, R36/37/38

(See SECTION 16 for full text of risk phrases)

2.2 GHS Label Elements

Hazard Pictogram

![Warning Symbol]

Signal Word: Warning

Restricted to use by dental professional only

Hazard Statements:

H315: Causes skin irritation. Category 2
H319: Causes serious eye irritation. Category 2.
H335: STOT SE Respiratory tract irritant. Category 3.
H302: Harmful if swallowed. Category 4
H312: Harmful in contact with skin. Category 4
H332: Harmful if inhaled. Category 4

Precautionary Statements

P261: Avoid breathing vapors.
P264: Wash hands thoroughly after handling.
P280: Wear protective gloves, lab coat and eye/face protection.
Safety Data Sheet

Trade Name: **FORENDO™ PASTE**, Calcium Hydroxide with Iodoform

P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing.

P301+P312: If swallowed, immediately call a Poison Control Center or doctor/physician.

P330: Rinse mouth.

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

P363: Wash contaminated clothing before reuse.

P304+340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.

### 3.0 Composition

#### 3.1 Chemical characterization of the preparation

Calcium hydroxide and Iodoform in a silicone-based paste.

#### 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>20-30 %</td>
<td>Xi (Irritant); R20/21/22, R36/37/38</td>
<td>Skin irritation, 2, H315 Eye irritation, 2, H319</td>
</tr>
<tr>
<td>75-47-8</td>
<td>Iodoform</td>
<td>30-40 %</td>
<td>Xn (Harmful); R41, R20/21/22</td>
<td>STOT SE Respiratory tract irritant, 4, H335 Acute toxicity (oral), 4, H302 Acute toxicity (dermal), 4, H312 Harmful if inhaled, 4, H332</td>
</tr>
</tbody>
</table>

### 4.0 First Aid Measures

#### 4.1 Special Instructions

Calcium hydroxide is a corrosive. Iodoform is considered harmful by inhalation, ingestion or contact with eyes or skin. However, when combined in a silicone-based paste, as in this product, they present a moderate hazard of irritation with prolonged exposure. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.

#### 4.2 Eye Contact

Move eyelids apart; 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 running water. Get medical attention if irritation persists.

#### 4.4 Ingestion

Rinse mouth with water. Do not induce vomiting unless directed by medical personnel. 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/or oxygen and seek immediate 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. May cause burns, 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
Toxic gases and vapors may be released under fire conditions.

5.4 Special protective equipment for fire-fighters
Self-contained breathing apparatus; full, protective clothing.

6.0 Accidental Release Measures

6.1 Personal precautions.
Wear chemical splash goggles, impervious gloves, lab coat with long sleeves and shoe covers.

6.2 Environmental precautions
Avoid release into the environment.

6.3 Method for clean up
Scrape / wipe up with damp paper towels. Wash spill area with detergent and water. Place spill and absorbent towels in covered 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.

7.2 Storage
Remove applicator tip immediately after use. Keep tightly capped in original container. Store at cool room temperature (<25°C) in a well-ventilated area. 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
Calcium hydroxide powder: PEL/TLV 5 mg/m³
Iodoform: 0.6 ppm (10 mg/m³)

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 calcium hydroxide may cause pH variation and iodoform may be harmful.

9.0 Physical and Chemical Properties

9.1 Characteristics
9.1.1 Appearance /Color / Physical state
Smooth, yellow paste

9.1.2 Odor
Characteristic, unpleasant, iodine odor

9.2 Important health, safety and environmental information
9.2.1 pH
pH > 12
Safety Data Sheet
Trade Name: **FORENDO™ PASTE**, Calcium Hydroxide with Iodoform

### 9.0 Physical Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.2.2 Boiling point</td>
<td>Decomposes</td>
</tr>
<tr>
<td>9.2.3 Flash point</td>
<td>Not combustible</td>
</tr>
<tr>
<td>9.2.4 Flammability (solid, gas)</td>
<td>Not combustible</td>
</tr>
<tr>
<td>9.2.5 Explosive properties</td>
<td>Not applicable</td>
</tr>
<tr>
<td>9.2.6 Oxidizing properties</td>
<td>Not determined</td>
</tr>
<tr>
<td>9.2.7 Vapor pressure</td>
<td>Not determined</td>
</tr>
<tr>
<td>9.2.8 Specific gravity</td>
<td>Not determined</td>
</tr>
<tr>
<td>9.2.9 Solubility in water</td>
<td>Nil</td>
</tr>
<tr>
<td>9.2.10 Partition coefficient</td>
<td>Not determined</td>
</tr>
<tr>
<td>9.2.11 Viscosity</td>
<td>Not determined</td>
</tr>
<tr>
<td>9.2.12 Vapor density</td>
<td>Not determined</td>
</tr>
<tr>
<td>9.2.13 Evaporation rate</td>
<td>Not determined</td>
</tr>
</tbody>
</table>

### 10.0 Stability and Reactivity

<table>
<thead>
<tr>
<th>Condition to avoid</th>
<th>Hazardous decomposition products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open flame, other ignition sources, temperature over 27°C, intense light.</td>
<td>Toxic iodine vapors, caustic fumes of calcium oxide, carbon monoxide, carbon dioxide, hydrogen iodide.</td>
</tr>
</tbody>
</table>

### 11.0 Toxicological Information

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.1 Acute toxicity</td>
<td>Iodoform, Oral rat LD₅₀: 355 mg/Kg</td>
</tr>
<tr>
<td></td>
<td>Calcium hydroxide, Oral Rat LD₅₀: 7340 mg/Kg</td>
</tr>
<tr>
<td>11.2 Irritation and corrosiveness</td>
<td>Forendo presents a minimal health hazard under normal conditions of dental practice. Prolonged exposure may cause burns/irritation of mucous membranes, eyes, skin, gastrointestinal tract, respiratory tract, dermatitis.</td>
</tr>
<tr>
<td>11.3 Sensitization</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>11.4 Sub-acute, sub-chronic and prolonged toxicity</td>
<td>Chronic exposure may cause skin rash, headache and skin eruptions in severe cases. Persons with pre-existing skin conditions may be more susceptible to the irritating effects of this material.</td>
</tr>
<tr>
<td>11.5 Carcinogenicity, Mutagenicity, Reproductive Toxicity</td>
<td>Not considered a carcinogen, mutagen, teratogen or a cause of reproductive toxicity.</td>
</tr>
<tr>
<td>11.6 Empirical data</td>
<td>Not available</td>
</tr>
<tr>
<td>11.7 Clinical Experience</td>
<td>Similar calcium hydroxide/iodoform preparations have been marketed to and used safely and effectively by dental professionals for many years.</td>
</tr>
</tbody>
</table>

### 12.0 Ecological Information

<table>
<thead>
<tr>
<th>Ecotoxicity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Avoid release into environment as calcium hydroxide may cause pH variation and iodoform may be harmful. Follow government regulations.</td>
</tr>
</tbody>
</table>
Safety Data Sheet
Trade Name: **FORENDO™ PASTE**, Calcium Hydroxide with Iodoform

### 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

IATA class

Not applicable

### 15.0 Regulatory Information

15.1 EU

Class Ila 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

R41: Risk of serious damage to eyes
R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.
R36/37/38: Irritating to eyes, respiratory system and skin.

16.2 Hazard Statements

H315: Causes skin irritation. Category 2
H319: Causes serious eye irritation. Category 2.
H335: STOT SE Respiratory tract irritant. Category 3.
H302: Harmful if swallowed. Category 4
H312: Harmful in contact with skin. Category 4
H332: Harmful if inhaled. Category 4

16.3 Precautionary Statements

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P301+P312: If swallowed, immediately call Poison Control Center or physician.
P330: Rinse mouth.
P302+P352: If on skin, wash with plenty of soap and water.
P363: Wash contaminated clothing before reuse.
P304+340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.

16.4 Restrictions on use

Calcium hydroxide/iodoform preparations, like Forendo, are to be used only by dental professionals who have been trained in their use.
### Safety Data Sheet

Trade Name: **FORENDO™ PASTE**, Calcium Hydroxide with Iodoform

#### 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.