


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

| 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, Importer   |   |   |                  |
| 1.3.1                                    | Manufacturer   |   |   |                  |
|  | Pulpdent Corporation   |   | Telephone: 1 617 926-6666   |                  |
|  | 80 Oakland Street, P.O. Box 780  |   | Fax: 1 617 926-6262   |                  |
|  | Watertown, MA 02472 USA  |   | Email: <a href="mailto:Pulpdent@pulpdent.com">Pulpdent@pulpdent.com</a>             |                  |
| 1.4                                      | Emergency Telephone Number   |   | 1-800-535-5053 (24 Hour / USA)  |                  |
| 1.5                                      | Authorized European Representative   |   |   |                  |
|  | International Business Solutions Ltd.  |   | Tel: 07989 407479 / Fax: 01256 350330   |                  |
|  | 54 Mayfield Ridge, Hatch Warren,   |   | Email: <a href="mailto:s.williams5@btconnect.co.uk">s.williams5@btconnect.co.uk</a> |                  |
|  | Basingstoke RG22 4RS UK  |   |   |                  |
| 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             |
|  |  | STOT SE Respiratory tract irritant        | 3   | H335             |
|  |  | Acute toxicity (oral)                     | 4   | H302             |
|  |  | Acute toxicity (dermal)                   | 4   | H312             |
|  |  | Harmful if inhaled                        | 4   | H332             |
| 2.1.2                                    | Classification according to Directive 67/548/EEC<br>(See SECTION 16 for full text of risk phrases) | Xi (Irritant) ; R41, R20/21/22, R36/37/38 |   |                  |
| 2.2 GHS Label Elements                   |  |   |   |                  |
|  | Hazard Pictogram   |   |   |                  |
|  |                 |   |   |                  |
|  | 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   |   |   |                  |

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**Precautionary Statements**

P261: Avoid breathing vapors.

P264: Wash hands thoroughly after handling.

P280: Wear protective gloves, lab coat and eye/face protection.

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

| CAS Number | Name of the Ingredient | Concentration | Classification per 67/548/EEC       | Classification per Regulation (EC) No.1278/2008 (CLP)  |
|------------|------------------------|---------------|-------------------------------------|--|
| 1305-62-0  | Calcium Hydroxide      | 20-30 %       | Xi (Irritant); R20/21/22, R36/37/38 | Skin irritation, 2, H315<br>Eye irritation, 2, H319  |
| 75-47-8    | Iodoform               | 30-40 %       | Xn (Harmful); R41, R20/21/22        | STOT SE Respiratory tract irritant, 4, H335<br>Acute toxicity (oral), 4, H302<br>Acute toxicity (dermal), 4, H312<br>Harmful if inhaled, 4, H332 |

**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 these ingredients are 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 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 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.

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|-----------|--|
| 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.   |

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| <b>5.0</b> | <b>Fire Fighting Measures</b> |  |
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| 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.               |

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| <b>6.0</b> | <b>Accidental Release Measures</b> |  |
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|-----|---------------------------|---|
| 6.1 | Personal precautions.     | Wear chemical splash goggles, impervious gloves, lab coat with long sleeves and shoe covers.  |
| 6.2 | Environmental precautions | None  |
| 6.3 | Method for clean up       | Scrape or wipe up with damp paper towels. Wash area of spill with detergent and water. Place spilled material and absorbent towels in covered container for disposal. |

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| <b>7.0</b> | <b>Handling and Storage</b> |  |
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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.  |
| 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   |

|            |  |  |
|------------|--|--|
| <b>8.0</b> | <b>Exposure Controls / Personal Protection</b> |  |
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|         |                                 |  |
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| 8.1     | Exposure limit values           | Calcium hydroxide powder: PEL/TLV 5 mg/m <sup>3</sup><br>Iodoform: 0.6 ppm (10 mg/m <sup>3</sup> )   |
| 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. 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 will 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 calcium hydroxide may cause pH variation and iodoform may be harmful.  |

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| 9.0 Physical and Chemical Properties |  |  |
|--------------------------------------|--|--|
| 9.1                                  | Appearance / Color                                     |  |
| 9.1.1                                | Color  | 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  |
| 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   | Not determined   |
| 9.2.8                                | Specific gravity                                       | Not determined   |
| 9.2.9                                | Solubility in water                                    | Nil  |
| 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                                    | Open flame and other ignition sources, temperature over 27°C, intense light.   |
| 10.2                                 | Materials to avoid                                     | Strong oxidizers, acetone.   |
| 10.3                                 | Hazardous decomposition products                       | Toxic iodine vapors, caustic fumes of calcium oxide, carbon monoxide, carbon dioxide, hydrogen iodide.   |
| 10.4                                 | Further information                                    | Stable under normal conditions.  |
| 11.0 Toxicological information       |  |  |
| 11.1                                 | Acute toxicity   | Iodoform, Oral rat LD <sub>50</sub> : 355 mg/Kg<br>Calcium hydroxide, Oral Rat LD <sub>50</sub> : 7340 mg/Kg   |
| 11.2                                 | Irritation and corrosiveness                           | 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. |
| 11.3                                 | Sensitization  | Not applicable.  |
| 11.4                                 | Sub-acute, sub-chronic and prolonged toxicity          | 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.                           |
| 11.5                                 | Carcinogenicity, Mutagenicity, Reproductive Toxicity   | Not considered a carcinogen, mutagen, teratogen or a cause of reproductive toxicity.   |

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| 11.6 | Empirical data      | Not available  |
| 11.7 | Clinical Experience | Similar calcium hydroxide/iodoform preparations have been marketed to and used by dental professionals for many years. Dentists' experience with many successful procedures is evidence of safe and effective treatment. |

## 12.0 Ecological Information

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|------|-------------|--|
| 12.1 | Ecotoxicity | Avoid release into environment as calcium hydroxide may cause pH variation and iodoform may be harmful. Follow government regulations. |
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## 13.0 Disposal Considerations

|      |             |   |
|------|-------------|---|
| 13.1 | Regulations | Follow all local and national government regulations in disposing material or contaminated packaging. |
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## 14.0 Transport Information

|      |                |  |
|------|----------------|--|
| 14.1 | Restrictions   | None. Not regulated.                   |
| 14.2 | UN Number      | None                                   |
| 14.3 | Technical name | Calcium hydroxide/iodoform preparation |
| 14.4 | Packing group  | Not applicable                         |
|      | 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 | R41: Risk of serious damage to eyes<br>R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.<br>R36/37/38: Irritating to eyes, respiratory system and skin.  |
| 16.2 | Hazard Statements          | H315: Causes skin irritation. Category 2<br>H319: Causes serious eye irritation. Category 2.<br>H335: STOT SE Respiratory tract irritant. Category 3.<br>H302: Harmful if swallowed. Category 4<br>H312: Harmful in contact with skin. Category 4<br>H332: Harmful if inhaled. Category 4   |
| 16.3 | Precautionary Statements   | P261: Avoid breathing vapors.<br>P264: Wash hands thoroughly after handling.<br>P280: Wear protective gloves, lab coat and eye/face protection.<br>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.<br>P301+P312: If swallowed, immediately call Poison Control Center or physician.<br>P330: Rinse mouth.<br>P302+P352: If on skin, wash with plenty of soap and water. |

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|      |   |  |
|------|---|--|
|      |   | P363: Wash contaminated clothing before reuse.<br>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.   |
| 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)<br>Occupational Safety and Health Administration (OSHA)<br>Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH).<br>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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