

Safety Data SheetTrade 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 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]	<u>Hazard Class</u>	<u>Hazard Category</u> <u>Hazard Statement</u>
		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	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****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

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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.

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 border="1"> <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>	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	20-30 %	Xi (Irritant); R20/21/22, R36/37/38	Skin irritation, 2, H315 Eye irritation, 2, H319	75-47-8	Iodoform	30-40 %	Xn (Harmful); R41, R20/21/22	STOT SE Respiratory tract irritant, 4, H335 Acute toxicity (oral), 4, H302 Acute toxicity (dermal), 4, H312 Harmful if inhaled, 4, H332
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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.															

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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.

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/m ³ Iodoform: 0.6 ppm (10 mg/m ³)
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	
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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
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, 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 ₅₀ : 355 mg/Kg Calcium hydroxide, Oral Rat LD ₅₀ : 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.
11.6	Empirical data	Not available
11.7	Clinical Experience	Similar calcium hydroxide/iodoform preparations have been marketed to and used safely and effectively by dental professionals for many years.
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.
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 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 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	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 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.

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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.
