

Safety Data Sheet

Premier® Enamelon® Fluoride Toothpaste

This industrial Material Safety Data Sheet is not intended for consumers and does not address consumer product use. For information regarding consumer application of this product, refer to the product label.

1. IDENTIFICATION

Premier Dental Products Company
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Plymouth Meeting, PA 19462
Phone: 610-239-6000 Fax: 610-239-6171
Emergency Phone: 610-239-6000

Product Name: Enamelon® Fluoride Toothpaste
CAS Number: Not applicable – product is a mixture

Recommended use of the chemical and restrictions on use

Recommended for Use: A fluoride toothpaste for anticavity, antigingivitis and sensitive teeth

2. HAZARDS IDENTIFICATION

Emergency Overview:

Opaque white paste
Mint taste and odor
Not a fire hazard; not an environmental hazard.
Slight eye irritation potential
Spills will cause slippery conditions

Potential Health Effects

Eye: Irritating, but will not cause permanent injury. Effects will be minimized with washing.

Skin Contact: Not a skin irritant.

Ingestion: Not considered toxic by ingestion.

Swallowing large amounts (tablespoonfuls) may result in abdominal discomfort.

Inhalation: None known.

Subchronic Effects/ Carcinogenicity: None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Ingredient (% by Weight)

Each Phase:

Binders, Thickeners, Abrasives	15 to 50%
Humectants	35 to 55%
Cleaning Agent, Fluoride	5 to 15%
Flavor, Sweetener, Color, Carrier	<5%

Workplace Considerations: Contains no other hazardous ingredients listed or defined in 29 CFR 1910, Subpart Z, at greater than 1% (and 0.1% for carcinogens).

Exempt from OSHA and WHMIS as a packaged consumer drug and cosmetic product.

4. FIRST AID MEASURES

Eyes: Flush with clean flowing water, low pressure and luke warm (not hot) if possible. Flush for 15 minutes or until irritation subsides. If irritation persists, seek medical attention.

Ingestion: Induce vomiting if large amounts are ingested. Keep airway clear. Seek medical attention.

NOTE TO PHYSICIAN: Large doses may cause alkalosis. Normal body mechanisms will handle the excretion of excess material and permit recovery. Treatment based on judgment of physician in response to reactions of patient.

5. FIRE-FIGHTING MEASURES

FLAMMABLE PROPERTIES FLAMMABLE LIMITS

Flashpoint: Not combustible LFL: Not applicable

Method Used: Not applicable UFL: Not applicable

Extinguishing Media: Non-combustible material.

Use extinguishing media appropriate for surrounding fire.

Fire-Fighting Instructions: Carbon Dioxide may be generated by thermal decomposition.

Firefighters should wear full bunker gear and a self-contained breathing apparatus in any closed place.

Unusual Fire and Explosion Hazards: None known.

6. ACCIDENTAL RELEASE MEASURES

Scoop up into a waste container.

Wash away small quantities of residual material with water.

Product spills will present a slipping hazard.

Use caution during cleanup and flush area thoroughly.

7. HANDLING AND STORAGE

Handling requirements: Avoid getting product in eyes

Storage conditions (For bulk containers and case quantities):

Keep containers closed and store product at ambient temperature.

Avoid freezing and excessive heat.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls: Not established for these products. Refer to Section 2 for ingredient exposure limits.

Respiratory Protection: None required for bulk paste. Refer to ingredient MSDS for respiratory protection requirements related to handling and exposure to specific ingredients.

Protective Gloves: Not normally required. Impervious gloves recommended if handling bulk product, as in spill cleanup for example.

Eye Protections: Not normally required. Safety glasses or goggles recommended when handling bulk product cleanup or transfer to containers.

Other Protective Clothing or Equipment: No special requirements.

Protective Work/Hygienic Practices: No special personal protection requirements with respect to product exposure beyond those mentioned above. Use good hygienic practices in the workplace.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Off white to white paste

Odor: Mint

Physical State: Solid/Paste

pH: @ 1:3 dilution: Range 4.5-5.5

Vapor Pressure: Not determined

Vapor Density: Not determined

Boiling Point: Not determined

Freezing /Melting Point: Not determined

Solubility in Water: Completely miscible and moderately soluble.

Specific Gravity (water = 1): Approximately 1.30

Molecular Weight: Not applicable (mixture)

10. STABILITY AND REACTIVITY

Chemical Stability: Stable.

Conditions to Avoid: For product integrity, avoid temperatures above 130°F.

Flavor in product is subject to degradation at prolonged elevated temperatures.

Incompatibility with Other Materials: Contact with acids will generate carbon dioxide.

Hazardous Decomposition Products: Thermal decomposition will result in the release of carbon monoxide and carbon dioxide.

Hazardous polymerization: Will not occur.

11. TOXICOLOGICAL INFORMATION

Eye Effects: Slight to moderate irritation possible.

Washing will decrease irritation effect and duration.

Skin: Not a primary skin irritant. Over-exposure may cause mild irritation.

Human long-term safety-in-use studies on similar toothpaste products resulted in no significant product-related oral irritation effects.

Acute Oral Effects: Considered practically non-toxic. Oral LD₅₀ > 5g/kg.

12. ECOLOGICAL INFORMATION

No data available.

13. DISPOSAL CONSIDERATIONS

Any disposal practice must be in compliance with local, state and federal regulations. Local and state laws may be different than federal. Be sure to consult with local and state agencies for specific rules. Landfill this product in accordance with all applicable regulations. Dilute and drain small amounts to sewer.

14. TRANSPORT INFORMATION

D.O.T. Shipping Name: Not regulated

Technical Shipping Name: Not applicable

D.O.T. Hazard Class: None

U.N./N.A. Number: None

Hazardous Substance/RQ: None

D.O.T. Label: None

D.O.T. Placard: None

ADR/RID:

UN no: None

Shipping Name: Not classified as dangerous in the meaning of transport regulations

ICAO/IATA:

UN no: None

IMO/IMDG:

UN no: None

15. REGULATORY INFORMATION

Consumer Use

U.S.A.: Regulated by Federal Food, Drug and Cosmetic Act, Consumer Product Safety Act, and Federal Hazardous Substances Act. As such, these products are exempt from the OSHA requirements under 29 CFR 1910.1200.

Canada: Regulated by the Food and Drugs Act and Hazardous Products Act, and as such, are exempt from WHMIS.

UK: Products sold in the UK (a member state of the European Union) are regulated under the EC Cosmetics Directive 76/768/EEC via The Cosmetic Products (Safety) Regulations of 1989 as amended.

The ingredients in these products are reported in the U.S. EPA TSCA Inventory, Canadian DSL, and European Inventory (EINECS).

Environmental

If these products become waste, they do not meet the definition of a hazardous waste by listing or characteristic.

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions which complete these regulations.

Refer to all applicable national, international and local regulations or provisions.

16. OTHER INFORMATION

Premier's revision date: 02/05/2015

Revision number: 2

Supplier's date: 07/07/2014

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