

**ENAMELON- stannous fluoride paste, dentifrice**  
**Premier Dental Products Company**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----  
**Enamelon Paste**

**Active ingredient**

Stannous fluoride 0.45% (0.16% w/v fluoride ion)

**Purpose**

Anticavity/Sensitivity Relief/Antigingivitis

**Uses**

- Aids in the prevention of cavities
- Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact
- Helps prevent gingivitis
- Helps interfere with the harmful effects of plaque associated with gingivitis

**Warnings**

**Keep out of the reach of children under 6 years of age.**

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. **Do not use if** gingivitis, bleeding, or redness persists for more than 2 weeks, see your dentist. See your dentist immediately if you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. **Stop use and ask a dentist if** the problem persists or worsens. Do not use this product for sensitivity relief longer than 4 weeks unless recommended by a dentist or doctor.

**Directions**

Adults and children 2 years of age or older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.

## **Other information**

- Products containing stannous fluoride may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.
- Do not use if foil seal on tube is broken or missing
- Keep tightly closed when not in use
- Store at controlled room temperature

## **Inactive ingredients**

Glycerin, polyethylene glycol, silica, calcium/sodium maleate methyl vinyl ether copolymer, cocamidopropyl betaine, calcium sulfate, poloxamer 407, dimethicone, lauroyl-sarcosine, titanium dioxide, flavor, acesulfame k, monosodium phosphate, sucralose

## **Questions or comments?**

Call toll-free 1-888-670-6100

Monday-Thursday 8am-5pm EST, Friday 8am-4pm EST

## **Distributed By**

Premier<sup>®</sup> Dental Products Company, Plymouth Meeting, PA 19462

[www.premusa.com](http://www.premusa.com) Part # 9007280 [www.enamelon.com](http://www.enamelon.com)

United States Patent Numbers : US 5,993,784, US 5,711,936, US 5,651,959 and other patents pending. Made in U.S.A.

Ultramulsion<sup>®</sup> is a registered trademark of WhiteHill Oral Technologies, Inc.

## **PRINCIPAL DISPLAY PANEL**

STRENGTHEN YOUR SMILE!

ACP<sup>™</sup> Enamel Therapy

Premier<sup>®</sup>

Enamelon<sup>®</sup>

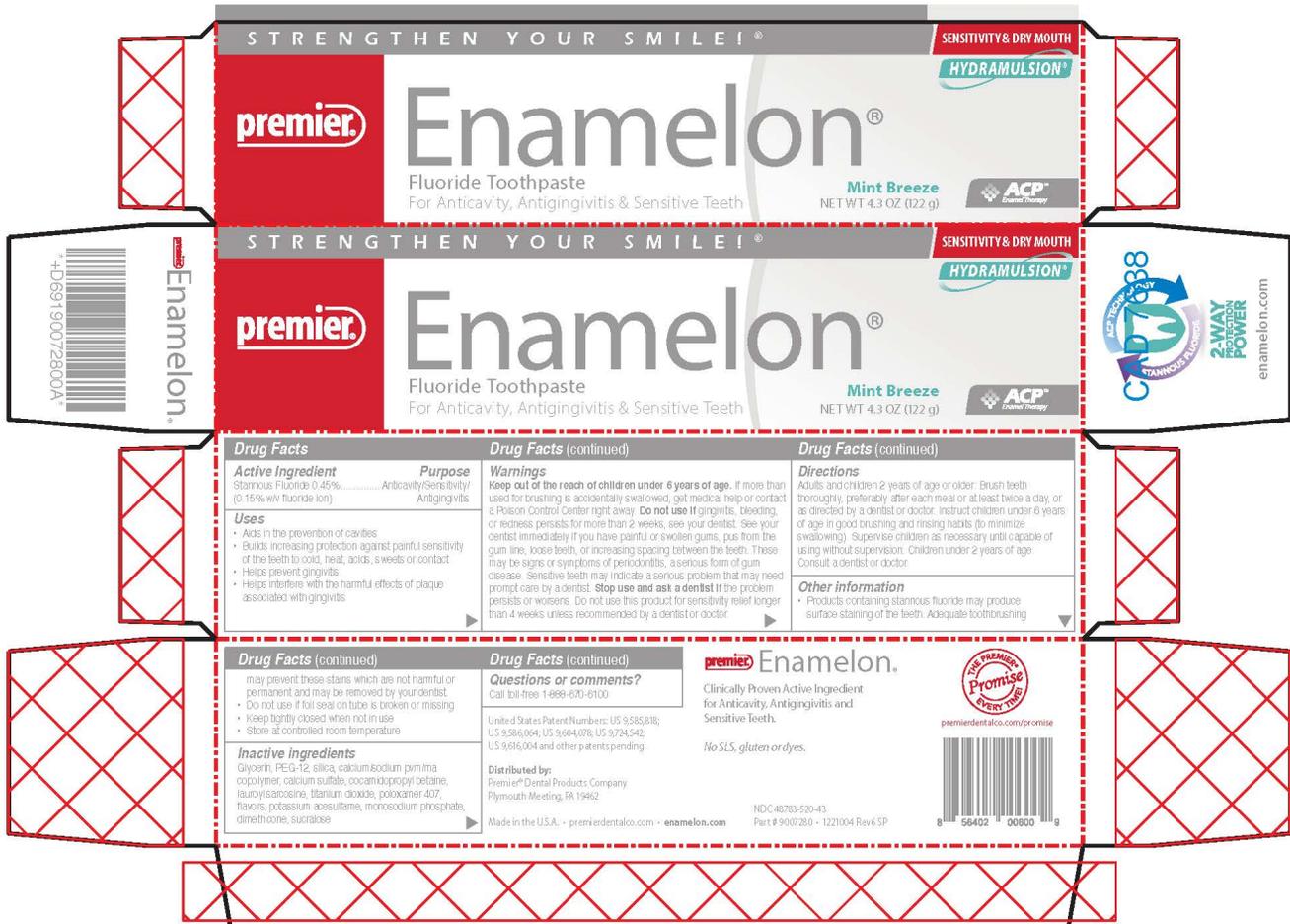
Mint Breeze

Fluoride Toothpaste NET WT 4.3 OZ (122 g)

For Anticavity, Antigingivitis & Sensitive Teeth

HYDRAMULSION<sup>®</sup>

NDC 48783-520-43



- Pantone 7472 C
- Pantone 186 C
- Pantone Cool Gray 7 C
- Pantone Cool Gray 1 C
- Pantone Blue 3005 C
- Pantone Purple 7678 C

## ENAMELON

stannous fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:48783-520
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>STANNOUS FLUORIDE</b> (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.00454 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CALCIUM/SODIUM MALEATE METHYL VINYL ETHER COPOLYMER (1000000 MW, 1900 MPAS AT 11%)</b> (UNII: 5216H1HX5F)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>CALCIUM SULFATE</b> (UNII: WAT0DDB505)	
<b>POLOXAMER 407</b> (UNII: TUF21VW3M2)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>LAUROYL SARCOSINE</b> (UNII: LJ19P3L6F)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>SODIUM PHOSPHATE, MONOBASIC</b> (UNII: 3980JIH2SW)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Mint Breeze)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48783-520-43	1 in 1 CARTON	01/01/2014	
1		122 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:48783-520-08	1 in 1 CARTON	01/01/2014	
2		21.2 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part355	01/01/2014	

**Labeler** - Premier Dental Products Company (014789663)

Revised: 1/2023

Premier Dental Products Company