

**BURTS BEES ENAMEL CARE- sodium fluoride paste, dentifrice**  
**Procter & Gamble Manufacturing 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.*

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**Burt's Bees® Enamel Care**

**Drug Facts**

**Active ingredient**

Sodium fluoride 0.243% (0.13% w/v fluoride ion)

**Purpose**

Anticavity toothpaste

**Use**

helps protect against cavities

**Warnings**

**Keep out of reach of children under 6 yrs of age.** If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- adults and children 2 yrs. & older: brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist
- do not swallow
- to minimize swallowing use a pea-sized amount in children under 6
- supervise children's brushing until good habits are established
- children under 2 yrs.: ask a dentist

**Inactive ingredients**

glycerin, water, hydrated silica, sodium cocoyl glutamate\*, cocamidopropyl betaine\*, flavor\*\*, xanthan gum, carrageenan, stevia rebaudiana extract, titanium dioxide

**Questions?**

1-855-248-5352

\*contains one of these ingredients  
\*\*Peppermint Oil and other Natural Flavor

DISTR. BY SUNFLOWER DISTRIBUTING  
LLC, CINCINNATI, OH 45202

### PRINCIPAL DISPLAY PANEL - 133 g tube in carton

**BURT'S**

**BEES®**

ENAMEL

CARE

FLUORIDE

Toothpaste

*Mountain*

*Mint*

NET WT 4.7 OZ (133 g)



# BURTS BEES ENAMEL CARE

sodium fluoride paste, dentifrice

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37000-922
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.3 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM COCOYL GLUTAMATE</b> (UNII: BMT4RCZ3HG)	
<b>STEVIA REBAUDIANA WHOLE</b> (UNII: 6U422Y08O2)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-922-47	1 in 1 CARTON	10/24/2018	
1		133 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:37000-922-85	1 in 1 CARTON	01/08/2019	
2		24 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	part355	10/24/2018	

**Labeler** - Procter & Gamble Manufacturing Company (004238200)

Revised: 2/2021

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