

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.

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

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

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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