

**WHITENING TOOTH POLISH- sodium fluoride paste**  
**Melaleuca, Inc.**

*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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**Fluoride Tooth Polish Cool Mint**

**Active ingredient**

Sodium Fluoride (0.243%)

**Purpose**

Anticavity

Use aids in the prevention of dental cavities

**Warnings**

**Keep out of 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. Warning: This product contains propolis, which can cause allergic reactions.

**Directions**

- adults and children 2 years of age and older: brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician
- instruct children under 6 years of age on 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 physician

**Inactive ingredients:** aloe barbadensis, ascorbyl palmitate, camellia sinensis leaf extract, commiphora myrrha oil, flavor, glycerin, hydrated silica, melaleuca alternifolia (tea tree) leaf oil, papain, poloxamer 407, potassium acesulfame, propolis extract, sodium alkyl sulfate, sodium benzoate, sorbitol, tetrapotassium pyrophosphate, tetrasodium pyrophosphate, titanium dioxide, tocopheryl acetate, water, xanthan gum, xylitol

COOL MINT

FLUORIDE  
**TOOTH POLISH**

WITH WHITENING PAIN, T40-C3® MELALEUCA OIL, PROPOLIS, AND MYRRH

NET WT 3.8 OZ (108 g)



**Drug Facts**

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Melaleuca, Inc., Idaho Falls, ID 83402-6003  
To order: 1-800-282-3000 • www.melaleuca.com  
Product of USA #5780 04/10U

NOT FOR RESALE IN CANADA



# WHITENING TOOTH POLISH

sodium fluoride paste

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-301
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.26244 g in 108 g

## Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MYRRH OIL (UNII: H74221J5J4)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
TEA TREE OIL (UNII: VIF565UC2G)	
PAPAIN (UNII: A236A06Y32)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (Cool Mint)	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-301-04	108 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	04/01/2010	

**Labeler** - Melaleuca, Inc. (139760102)

## Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc._Knoxville		805617610	manufacture(54473-301)

Revised: 3/2018

Melaleuca, Inc.