

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.

Fluoride Tooth Polish Cool Mint Content of Label

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 PAPAIN, T40-C3® MELALEUCA OIL, PROPOLIS, AND MYRRH

NET WT 3.8 OZ (108 g)



Drug Facts

| Active ingredient | Purpose |
|-----------------------------------|------------|
| Sodium fluoride (0.243% w/w)..... | Anticavity |

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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:54473-188 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | SODIUM FLUORIDE | 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: 059QF0K00R) | |
| 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:54473-188-04 | 108 g in 1 TUBE | | |

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 |

Revised: 2/2011

Melaleuca, Inc.