

**SENSITIVE TOOTH POLISH- potassium nitrate and sodium fluoride paste, dentifrice  
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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**Sensitive Fluoride Tooth Polish content of label**

**Active ingredients**

Potassium nitrate (5.0% w/w)

Sodium fluoride (0.243% w/w)

**Purpose**

Antisensitivity

Anticavity

**Uses**

- when used regularly, builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact
- aids in the prevention of cavities

**Warnings**

**When using this product** do not use longer than four weeks unless recommended by a dentist

**Stop use and ask a dentist if** problem lasts or gets worse. Sensitive teeth may indicate a serious problem that may need prompt care.

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

**Directions**

- adults and children 12 years of age and older: Apply at least a 1-inch strip of product onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute, preferably after each meal or at least twice a day (morning and evening) or as recommended by a dentist or physician. Make sure to brush all sensitive areas of the teeth.
- children under 12 years of age: consult a dentist or physician

**Other information**

This product contains papain, which may cause allergic reactions

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

CLEAN MINT

REDUCES SENSITIVITY • FIGHTS CAVITIES • FIGHTS TARTAR • REMOVES PLAQUE •  
FRESHENS BREATH • NATURALLY WHITENS TEETH

FLUORIDE  
**TOOTH POLISH**  
FOR SENSITIVE TEETH

NET WT 3.8 OZ (108 g)



FLUORIDE

**TOOTH POLISH**

FOR SENSITIVE TEETH

WITH REGULAR BRUSHING:

- ✓ Soothes Sensitive Teeth
- ✓ Fights Cavities
- ✓ Whitens Teeth
- ✓ Freshens Breath
- ✓ Fights Tartar
- ✓ Removes Plaque

**Drug Facts**

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With whitening papain, T40-C3® Melaleuca Oil, xylitol, and myrrh.

Melaleuca, Inc., Idaho Falls, ID 83402-6003  
To order: 1-800-282-3000 • www.melaleuca.com  
Product of USA #8697 01/12U

NOT FOR RESALE IN CANADA



potassium nitrate and sodium fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54473-205
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.26244 g in 108 g
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM NITRATE	5.4 g in 108 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
GLYCERIN (UNII: PDC6A3C0OX)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
MYRRH OIL (UNII: H74221J5J4)	
PAPAIN (UNII: A236A06Y32)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SORBITOL (UNII: 506T60A25R)	
TEA TREE OIL (UNII: VIF565UC2G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	
ZINC CITRATE (UNII: K72I3DEX9B)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:54473-205-04	108 g in 1 TUBE		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part356	01/03/2012		

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

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Melaleuca, Inc.		139760102	manufacture

Revised: 11/2011

Melaleuca, Inc.