

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.

Sensitive Fluoride Tooth Polish

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)



Melaleuca

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				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-302	
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	
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)		POTASSIUM NITRATE	5.4 g in 108 g	
Inactive Ingredients				
Ingredient Name			Strength	
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				
Color		Score		
Shape		Size		
Flavor	MINT (Clean Mint)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:54473-302-04	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 not final		part356	01/03/2012	

Labeler - Melaleuca, Inc. (139760102)

Establishment			
Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		805617610	manufacture(54473-302)