

**EXCEED TOTAL CARE SENSITIVE PEPPERMINT 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.

Exceed Total Care Sensitive Tooth Polish - Peppermint

Uses

- aids in the prevention of dental cavities
- helps reduce painful sensitivity of the teeth to cold, heat, acids, sweets or contact

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.
- Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or doctor.

Directions

- adults and children 12 years of age or older: apply at least a 1-inch strip of the tooth polish onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute twice a day (morning and evening) or as recommended by a dentist or doctor. Be sure to brush all sensitive areas of the teeth.
- children under 12 years of age: consult a dentist or doctor

Inactive Ingredients water, hydrated silica, glycerin, sorbitol, flavor, xanthan gum, stevia leaf extract, propanediol, poloxamer 407, zinc citrate, tetrasodium pyrophosphate, titanium dioxide, lauramidopropyl betaine, benzyl alcohol, sodium hydroxide, melaleuca alternifolia (tea tree) leaf oil.

Active Ingredient Purpose

Sodium fluoride (0.243%w/w).....Anticavity

Potassium nitrate (5.0%w/w).....Antisensitivity

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.

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+ FLUORIDE
PEPPERMINT

EXCEED™

TOTAL CARE SENSITIVE TOOTH POLISH

Prevents Cavities
Naturally Whitens
Soothes Sensitive Teeth
Made with Gentle,
Plant-Derived Cleansers



NET WT 3.3 OZ (93.5 g)

FREE FROM

Artificial Sweeteners,
Dyes, and Preservatives

Drug Facts

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Sodium fluoride (0.243% w/w)	Anticavity
Potassium nitrate (5.0% w/w)	Antisensitivity

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Inactive ingredients water, hydrated silica, glycerin, sorbitol, flavor, xanthan gum, xylitol, sodium methyl cocoyl taurate, cellulose gum, stevia leaf extract, propanediol, poloxamer 407, zinc citrate, tetrasodium pyrophosphate, titanium dioxide, lauramidopropyl betaine, benzyl alcohol, sodium hydroxide, melaleuca alternifolia (tea tree) leaf extract

Metaleuca, Inc.
Idaho Falls, ID 83402
To order: 1-800-282-3000
Metaleuca.com
N° 42997 10/21 U
NOT FOR RESALE



not recommended

EXCEED TOTAL CARE SENSITIVE PEPPERMINT TOOTH POLISH

potassium nitrate and sodium fluoride paste, dentifrice

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:54473-340
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)			POTASSIUM NITRATE	0.2272 g in 93.5 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)			SODIUM FLUORIDE	4.675 g in 93.5 g
Inactive Ingredients				
Ingredient Name				Strength
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
PROPANEDIOL (UNII: 5965N8W85T)				
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)				
WATER (UNII: 059QF0KO0R)				
XANTHAN GUM (UNII: TTV12P4NEE)				
XYLITOL (UNII: VCQ006KQ1E)				
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)				
ZINC CITRATE (UNII: K72I3DEX9B)				
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)				
REBAUDIOSIDE A (UNII: B3FUD0528F)				
SORBITOL (UNII: 506T60A25R)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)				
GLYCERIN (UNII: PDC6A3C0OX)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
LAURAMIDOPROPYL BETAINE (UNII: 23D6XVI233)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
Product Characteristics				
Color			Score	
Shape			Size	
Flavor		PEPPERMINT	Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-340-01	93.5 g in 1 TUBE; Type 0: Not a Combination Product	11/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/08/2022	

Labeler - Melaleuca, Inc (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc		805617610	manufacture(54473-340)

Revised: 11/2022

Melaleuca, Inc