

EXCEED TOTAL CARE SENSITIVE SPEARMINT 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

Uses

- aids in the prevention of dental cavaties
- helps reducee 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 accidently swallowed, get medical help or contact a Poison Control Center right away.
- Sensitivt 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 strup 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, tetrasocium pyrophosphate, titanium dioxide, lauramidopropyl betaine, benzyl alcohol, sodium hydroxide, melaleuca alternifolia (tea tree) leaf oil.

Active Ingredient Purpose

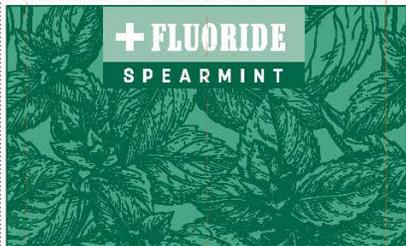
Sodium fluoride (0.243%w/w).....Anticavity

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 accidently swallowed, get medical help or contact a Poison Control Center right away.

Do not use this product longer than 4 weeks unless recommended by a dentist or doctor.

Essej Propack
CONFIDENTIAL
Date _____ Sign _____



EXCEED™

TOTAL CARE SENSITIVE TOOTH POLISH

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



Graphics area-color ok / text not recommended

FREE FROM
Artificial Sweeteners,
Dyes, and Preservatives

Drug Facts

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

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, xylitol, sodium methyl cocoyl taurate, cellulose gum, stevia leaf extract, propenediol, poloxamer 407, zinc citrate, tetrasodium pyrophosphate, titanium dioxide, lauryl dimethylammonium propyl betaine, benzyl alcohol, sodium hydroxide, melaleuca alternifolia (tea tree) leaf oil

Melaleuca, Inc.
Idaho Falls, ID 83402
To order: 1-800-282-3000
Melaleuca.com
N# 42896 10/21 U
NOT FOR RESALE



VOID OF INK

EXCEED TOTAL CARE SENSITIVE SPEARMINT TOOTH POLISH

potassium nitrate and sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-337
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:Q80VPU4080)	SODIUM FLUORIDE	4.675 g in 93.5 g

Inactive Ingredients

Ingredient Name	Strength
HYDRATED SILICA (UNII: Y607T4G8P9)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPANEDIOL (UNII: 5965N8W85T)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZ17B19X)	
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	SPEARMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-337-04	93.5 g in 1 TUBE; Type 0: Not a Combination Product	01/08/2022	

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(54473-337)

Revised: 4/2022

Melaleuca, Inc