

PINE SALT - sodium fluoride paste, dentifrice
Kareway Product, 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.

Drug Facts

Active ingredient
sodium fluoride 0.22%

Purpose
Anticavity

Uses
helps protect against cavities

Warnings
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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.

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
Children 2 to 6 years	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).
Children under 2 years	ask a dentist or physician

Inactive ingredients
di water, sorbitol, hydrated silica, sodium methyl cocoyl taurate, peg-32, sodium lauryl sulfate, baked sodium chloride, flavor, cellulose gum, songyum capsule, sodium saccharin, disodium phosphate, menthol capsule, methyl paraben, pine extract, tranexamic acid, yellow no.10, blue no.1

Package label
Pine Salt Toothpaste



PINE SALT

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0043
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	2.2 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
PEG-32 STEARATE (UNII: 33GX5WQC0M)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)

MENTHOL (UNII: L7T10EIP3A)

METHYLPARABEN (UNII: A2I8C7H9T)

PINUS STROBUS BARK (UNII: 8PJ4761097)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0043-6	1 in 1 BOX		
1		170 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/22/2011	

Labeler - Kareway Product, Inc. (121840057)

Revised: 8/2011

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