LONG-LASTING WICKED FRESH - COOL PEPPERMINT- sodium monofluorophosphate paste, dentifrice Tom's of Maine, 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.

natural care Tom's of Maine®

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76% (0.14% w/v fluoride ion)

Purpose

Anticavity

Use

aids in the prevention of dental cavities.

Warnings

Keep out of the reach of children under 6 years of age.

If more than used for brushing is accidentally swallowed, get medical help or dial (412) 390-3381 right away (Poison Control Center).

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

glycerin, water, hydrated silica, calcium carbonate, xylitol, natural flavors, sodium lauryl sulfate, *Chondrus crispus* (carrageenan), *Glycyrrhiza uralensis* (licorice) root extract.

Questions?

1-800-FOR-TOMS M-F 8:30 a.m.-5 p.m. ET

© 2009 Tom's of Maine, Inc., 302 Lafayette Ctr., Kennebunk, ME 04043 Made in U.S.A.

PRINCIPAL DISPLAY PANEL - 147.4g Box

cool peppermint

new!

natural care Tom's of Maine®

LONG-LASTING

wicked fresh!

fresh breath anticavity toothpaste with fluoride

NET WT 147.4g (5.2 OZ)



LONG-LASTING WICKED FRESH - COOL PEPPERMINT

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-146
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Sodium monofluorophosphate (UNII: C810JCZ56Q) (Sodium cation - UNII: LYR4M0NH37)	So dium mo no fluo ro pho sphate	0.0076 g in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
Glycerin (UNII: PDC6A3C0OX)		
Water (UNII: 059QF0KO0R)		
Calcium carbonate (UNII: H0G9379FGK)		
Xylitol (UNII: VCQ006KQ1E)		
Silicon Dioxide (UNII: ETJ7Z6XBU4)		
Carrageenan (UNII: 5C69 YCD2YJ)		
Peppermint Oil (UNII: AV092KU4JH)		
Menthol (UNII: L7T10 EIP3A)		
Sodium Lauryl Sulfate (UNII: 368GB5141J)		
Anise Seed (UNII: 21C2F5E8RE)		
Eucalyptus Oil (UNII: 2R04ONI662)		
Licorice (UNII: 61ZBX54883)		
Vanillin (UNII: CHI530446X)		
Cinnamyl Alcohol (UNII: SS8 YOP444F)		
Clove oil (UNII: 578389 D6 D0)		

Product Characteristics		
Color	WHITE	Score
Shape		Size
Flavor	PEPPERMINT (Cool Peppermint)	Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51009-146-06	1 in 1 BOX		
1	147.4 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	11/30/2009	

Establishment			
Name	Address	ID/FEI	Business Operations
Tom's of Maine, Inc.		052764354	MANUFACTURE

Revised: 11/2009 Tom's of Maine, Inc.