

**SIMPLY WHITE SWEET MINT- sodium fluoride 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.

SIMPLY WHITE®

Drug Facts

Active ingredient

Sodium fluoride 0.24% (0.15% w/v fluoride ion)

Purpose

Anticavity

Use

helps protect against 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

hydrated silica, water, sorbitol, glycerin, xylitol, sodium lauryl sulfate, natural flavors, xanthan gum, *Chondrus crispus* (carrageenan).

Questions?

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

PRINCIPAL DISPLAY PANEL - 133.2g Tube Carton

new!

SINCE 1970

Tom's
OF MAINE™

natural

SIMPLY WHITE®

whitening | cavity protection | fresh breath

fluoride toothpaste

sweet mint gel

NET WT 133.2g (4.7 OZ)

SIMPLY WHITE®
Smile with Natural Confidence.
The key to our effective formula is our natural silicas, derived from sand to improve cleaning and to gently whiten without bleaching ingredients or harsh abrasives. Simply White® toothpaste helps to restore the natural whiteness of your teeth. Try Simply White® for a bright, healthy smile that shows your natural confidence!

© 2010 Tom's of Maine, Inc., 302 Lafayette Ctr., Kennebunk, ME 04043 Made In U.S.A.

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whitening | cavity protection | fresh breath
fluoride toothpaste
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Drug Facts	
Active ingredient Sodium fluoride 0.24% to 0.15%, w/v fluoride ion	Purpose Anticavity
Use helps protect against 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 call (417) 360-5381 right away (Poison Control Center).	
Directions	

Drug Facts (continued)	
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 supervised child's brushing and rinsing for no more than 2 minutes.
children under 2 years:	use a smear of paste on.
Inactive ingredients hydrated silica, water, sorbitol, glycerin, xylitol, sodium lauryl sulfate, natural flavors, xanthan gum, Chlorhexidine Digluconate.	
Questions? 1-800-FOR-TOMS M-F 8:30 a.m.-5 p.m. ET	

Tom's Mission Day 2008
Company Volunteer Day with Nature Conservancy

What makes a product good? At Tom's, it includes how we make it.

- No animal testing or animal ingredients.
- We share every ingredient, its purpose, and its source at www.tomsofmaine.com.
- Sustainable practices are a priority in every aspect of our business.
- No artificial colors, flavors, or preservatives.
- We strive to maximize recycled content and recyclability of our packaging.
- 5% (12 days) of employee time to volunteering. 10% of profits to human and environmental goodness.

Visit www.tomsofmaine.com or find us on: Facebook Twitter YouTube

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0 77326 14906 5

SIMPLY WHITE SWEET MINT

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-149
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.0024 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
ANISE (UNII: 21C2F5E8RE)	
VANILLIN (UNII: CHI530446X)	
CLOVE OIL (UNII: 578389D6D0)	
ZINGERONE (UNII: 4MMW850892)	
PIPERONAL (UNII: KE109YAK00)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (Sweet Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51009-149-06	1 in 1 CARTON	03/12/2010	12/30/2025
1		133.2 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH			

OTC MONOGRAPH FINAL	part355	03/12/2010	12/30/2025
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Labeler - Tom's of Maine, Inc. (052764354)

Revised: 9/2023

Tom's of Maine, Inc.