

**CLEAN AND GENTLE 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.

**Tom's
OF MAINE
CLEAN & GENTLE
fluoride toothpaste**

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76% (0.13% w/v fluoride ion)

Purpose

Anticavity

Use

helps protect against cavities

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 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, calcium carbonate, hydrated silica, organic *Aloe barbadensis* (aloe) leaf juice, xylitol, *Chondrus crispus* (carrageenan), *Acacia senegal* (acacia) gum, glycyrrhizic acid, *Mentha piperita* (peppermint) oil.

Questions?

1-800-FOR-TOMS (1-800-367-8667) M - F 8:30 a.m. - 5:30 p.m. ET

PRINCIPAL DISPLAY PANEL - 133 g Carton

SINCE 1970

**Tom's
OF MAINE™**

with fluoride | natural

CLEAN & GENTLE

SLS-free | anticavity | whitening | fresh breath

fluoride toothpaste

peppermint

NET WT 4.7 OZ (133 g)



natural
with fluoride

CLEAN & GENTLE





SLS-free
anticavity
whitening
fresh breath

fluoride toothpaste
peppermint



NET WT 4.7 OZ (133 g)

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

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



You asked – we listened!
This tube is easier to use than our previous tube. Learn more about how this tube reinforces our commitment to environmental stewardship at: www.tomsomaine.com

Find us on:





Tom's of Maine™ Goodness Day



with fluoride | natural

CLEAN & GENTLE

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peppermint



NET WT 4.7 OZ (133 g)

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302 Lafayette Ctr.
Kennebunk, ME 04043
Made in U.S.A. 

CLEAN AND GENTLE PEPPERMINT

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-107
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)	Sodium Mono fluorophosphate	0.0076 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Calcium carbonate (UNII: H0G9379FGK)	
Hydrated silica (UNII: Y6O7T4G8P9)	
Xylitol (UNII: VCQ006KQ1E)	
Carrageenan (UNII: 5C69YCD2YJ)	
Peppermint Oil (UNII: AV092KU4JH)	
Glycyrrhizin (UNII: 6FO62043WK)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	

Product Characteristics

Color	WHITE (Off-white)	Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51009-107-47	1 in 1 CARTON		
1		133 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	02/14/2011	

Establishment

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

Revised: 2/2011

Tom's of Maine, Inc.