# TOMS WHOLE CARE SPEARMINT FIGHTS CAVITIES WHITENING FRESH BREATH HELPS FIGHT TARTAR- 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.

-----

 $Tom's_{\,@}\ Whole\ Care^{\,@}\ Spearmint\ Gelfights\ cavities\ |\ whitening\ |\ fresh\ breath\ |\ helps\ fight\ tartar$ 

**Drug Facts** 

#### **Active ingredient**

Sodium monofluorophosphate 0.76% (0.14% 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**

water, hydrated silica, sorbitol, xylitol, glycerin, natural flavor<sup>1</sup>, sodium lauryl sulfate, zinc citrate, xanthan gum, carrageenan.

#### Questions?

1-800-FOR-TOMS (1-800-367-8667)

<sup>1</sup> spearmint oil and other natural flavor

#### PRINCIPAL DISPLAY PANEL - 133 g Tube Carton

SINCE 1970 Tom's ® OF MAINE

with fluoride | natural

WHOLE CARE®

#### fluoride toothpaste

fights cavities | whitening | fresh breath | helps fight tartar no artificial dyes or sweeteners

#### spearmint gel

NET WT 4.7 OZ (133 g)



# TOMS WHOLE CARE SPEARMINT FIGHTS CAVITIES WHITENING FRESH BREATH HELPS FIGHT TARTAR

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-207
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Sodium monofluorophosphate (UNII: C810JCZ56Q) (Fluoride ion - UNII:Q80VPU408O)	Fluoride ion	1.4 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
Hydrated Silica (UNII: Y6O7T4G8P9)		
Sorbitol (UNII: 506T60A25R)		
Xylitol (UNII: VCQ006KQ1E)		
Glycerin (UNII: PDC6A3C0OX)		
Sodium Lauryl Sulfate (UNII: 368GB5141J)		
Spearmint Oil (UNII: C3M81465G5)		
ZINC CITRATE TRIHYDRATE (UNII: GNM26 GAX7R)		
XANTHAN GUM (UNII: TTV12P4NEE)		
Peppermint Oil (UNII: AV092KU4JH)		
Carrageenan (UNII: 5C69YCD2YJ)		

Product Characteristics			
Color	WHITE (Off white)	Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:51009-207-47	1 in 1 CARTON	08/12/2014	
1		133 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 FINAL	part355	08/12/2014	

## Labeler - Tom's of Maine, Inc. (052764354)

### Establishment

Name	Address	ID/FEI	Business Operations
Tom's of Maine, Inc.		829517189	MANUFACTURE(51009-207)

Revised: 9/2019 Tom's of Maine, Inc.