

**CHILDRENS OUTRAGEOUS ORANGE MANGO- 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.*

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**Tom's™  
OF MAINE**

***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, natural flavors, *Chondrus crispus* (carrageenan), sodium lauryl sulfate.

**Questions?**

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

**PRINCIPAL DISPLAY PANEL - 119 g Tube**

**SINCE 1970**

**Tom's™  
OF MAINE**

**ADA**

**Accepted**

American  
Dental  
Association®

natural  
***children's***

prevents  
cavities

tastes great

**fluoride toothpaste**

***outrageous***  
***orange mango™***

NET WT 4.2 OZ (119 g)



## CHILDRENS OUTRAGEOUS ORANGE MANGO

sodium monofluorophosphate paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51009-127
<b>Route of Administration</b>	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: 059QF0K00R)	
Calcium carbonate (UNII: H0G9379FGK)	
Hydrated silica (UNII: Y6O7T4G8P9)	
Orange (UNII: 5EVU04N5QU)	
Carrageenan (UNII: 5C69YCD2YJ)	
sodium lauryl sulfate (UNII: 368GB5141J)	

  

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor	ORANGE (Orange-mango with other natural fruit flavors)	Imprint Code	
Contains			

  

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51009-127-04	1 in 1 CARTON		
1		113 g in 1 TUBE		

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/30/2010	

CHILDRENS OUTRAGEOUS ORANGE MANGO			
sodium monofluorophosphate paste, dentifrice			

  

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-830
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
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Water</b> (UNII: 059QF0K00R)	
<b>Calcium carbonate</b> (UNII: H0G9379FGK)	
<b>Hydrated silica</b> (UNII: Y6O7T4G8P9)	
<b>Orange</b> (UNII: 5EVU04N5QU)	
<b>Carrageenan</b> (UNII: 5C69YCD2YJ)	
<b>sodium lauryl sulfate</b> (UNII: 368GB5141J)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE (Orange-mango with other natural fruit flavors)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51009-830-94	119 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/30/2010	

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

## Establishment

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

Revised: 8/2010

Tom's of Maine, Inc.