

**OUTRAGEOUS ORANGE ANTICAVITY - OFT51 MRT- 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.

Outrageous Orange Anticavity - OFT51 MRT

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

glycerin, water, calcium carbonate, hydrated silica, benzyl alcohol, sodium lauryl sulfate, carrageenan, natural flavor, *Citrus limon* (Lemon) juice, *Mangifera indica* (Mango) juice, *Citrus aurantium dulcis* (Orange) juice, *Ananas sativus* (Pineapple) fruit juice, *Fragaria ananassa* (Strawberry) fruit juice.

Questions?

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

PRINCIPAL DISPLAY PANEL - 144 g Tube Label

20% more!
vs. 4.2oz size

SINCE 1970
Tom's
OF MAINE®

ADA
Accepted
American
Dental
Association®

natural
children's

fluoride toothpaste

fight's cavities
tastes great
dye free

with real
fruit juice!

outrageous
orange mango

NET WT 5.1 OZ (144 g)



20% more!
vs. 4.2oz size



natural

children's

fluoride toothpaste

fights cavities
 tastes great
 dye free



with real fruit juice!

outrageous
orange mango

NET WT 5.1 OZ (144 g)

M U GLUTEN-FREE

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We never use artificial dyes, sweeteners, flavors, preservatives, or animal testing. Learn more about our Stewardship Model and what we mean by "natural" at: www.tomsomaine.com

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P9937057 1304

TWIST OFF CAP AND REMOVE FOIL SEAL • DO NOT USE IF SEAL IS NOT INTACT



Helps prevent cavities



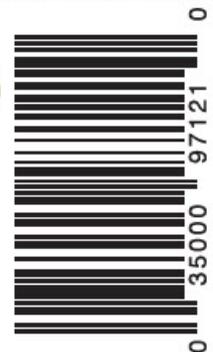
Once empty, close cap and recycle with #2 plastics.

Certified



Corporation

BPA-Free Tube



We've switched to a recyclable tube! Learn more at www.tomsomaine.com

OUTRAGEOUS ORANGE ANTICAVITY - OFT51 MRT

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-911
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0014 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
ORANGE (UNII: 5EVU04N5QU)	
LEMON JUICE (UNII: AGN709ANTJ)	
MANGO JUICE (UNII: IU6I1JNV24)	
ORANGE JUICE (UNII: 5A9KE2L9L3)	
PINEAPPLE JUICE (UNII: O4KOG0B1KC)	
STRAWBERRY JUICE (UNII: U8NS58UGW0)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	ORANGE (Orange Mango)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51009-911-51	144 g in 1 TUBE; Type 0: Not a Combination Product	11/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	11/15/2019	

Revised: 11/2019

Tom's of Maine, Inc.