SILLY STRAWBERRY ANTICAVITY - BFT51 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.

Silly Strawberry Anticavity - BFT51 MRT 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 flavor 1 , carrageenan, sodium lauryl sulfate

1 strawberry juice and other natural flavor

Questions?

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

PRINCIPAL DISPLAY PANEL - 144 g Tube Label

Original Formula

SINCE 1970 Tom's OF MAINE_®

ADA

Accepted

American

Dental

Association ®

natural

children's

fluoride toothpaste

fights cavities

tastes great

dye free

silly strawberry

NET WT 5.1 OZ (144 g)



SILLY STRAWBERRY ANTICAVITY - BFT51 MRT

sodium monofluorophosphate paste, dentifrice

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-910	
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)			
STRAWBERRY (UNII: 4J2TY8Y81V)			
LEMON JUICE (UNII: AGN709ANTJ)			
MANGO JUICE (UNII: IU611JNV24)			
ORANGE JUICE (UNII: 5A9KE2L9L3)			
PINEAPPLE JUICE (UNII: O4KOG0B1KC)			
STRAWBERRY JUICE (UNII: U8NS58UGW0)			

Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor	STRAWBERRY	Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:51009-910- 51	144 g in 1 TUBE; Type 0: Not a Combination Product	11/15/2019		
2	NDC:51009-910- 10	1 in 1 CARTON	01/14/2013		
2		21 g in 1 TUBE; Type 0: Not a Combination Product			
3	NDC:51009-910- 42	119 g in 1 TUBE; Type 0: Not a Combination Product	08/16/2010		
4	NDC:51009-910- 52	2 in 1 CARTON	11/04/2020	01/29/2023	
4		144 g in 1 TUBE; Type 0: Not a Combination Product			

5	NDC:51009-910- 01	21 g in 1 TUBE; Type 0: Not a Combination Product	04/01/2015	03/30/2020
6	NDC:51009-910- 53	3 in 1 CARTON	02/15/2022	03/21/2024
6		150 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	08/15/2010	

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Team Technologies, Inc		079527756	PACK(51009-910)	

Revised: 9/2023 Tom's of Maine, Inc.