

**CHILDRENS SILLY STRAWBERRY- 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
natural
children's
silly strawberry**

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 - 24.7 g Carton

SINCE 1970

Tom's™
OF MAINE

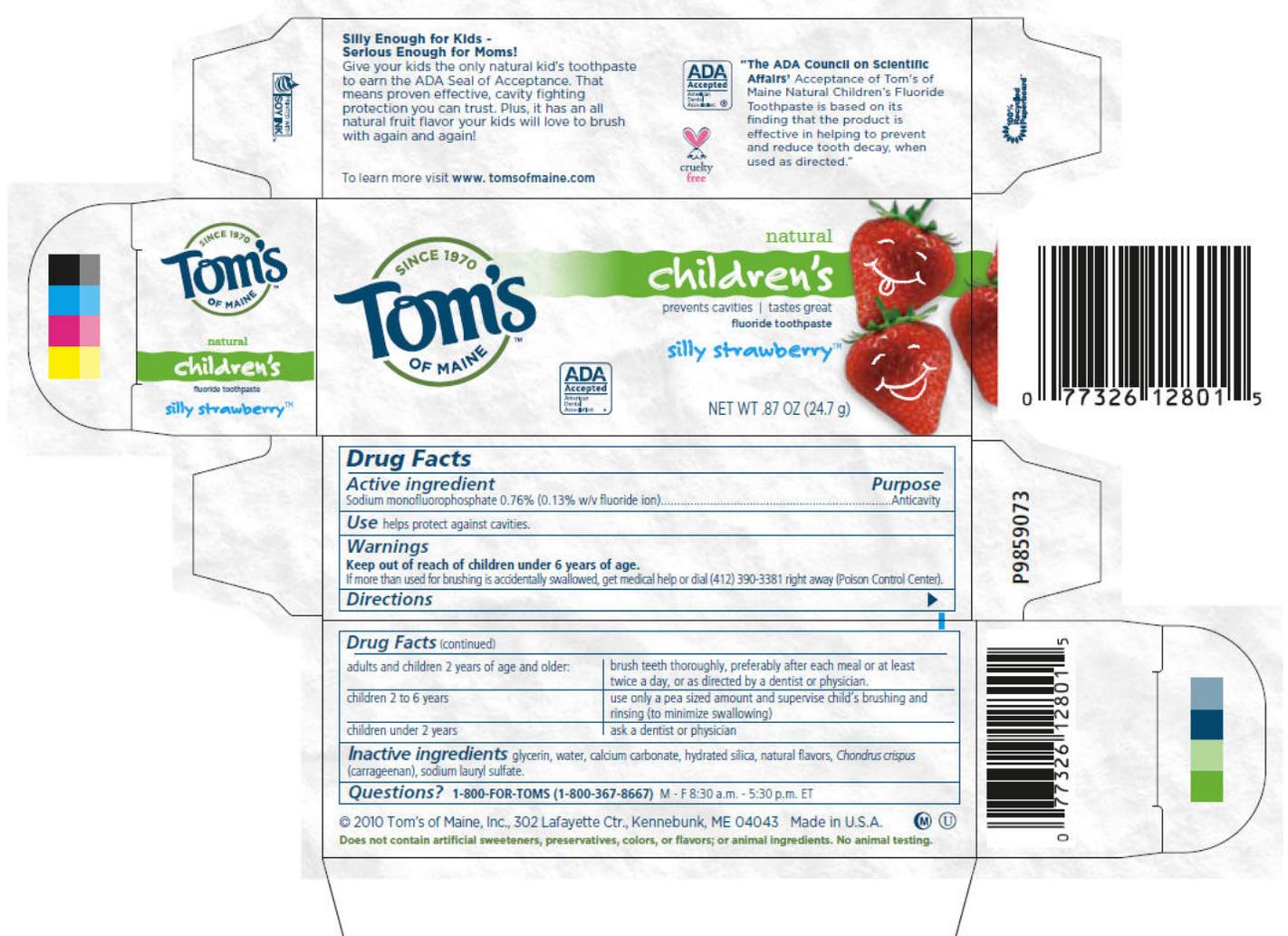
natural
children's

prevents cavities, tastes great
fluoride toothpaste

silly strawberry™

ADA
Accepted
American
Dental
Association®

NET WT .87 OZ (24.7 g)



CHILDRENS SILLY STRAWBERRY

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-128
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Mono fluorophosphate (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)	
Strawberry (UNII: 4J2TY8Y81V)	
Carrageenan (UNII: 5C69YCD2YJ)	
sodium lauryl sulfate (UNII: 368GB5141J)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	STRAWBERRY (with other natural fruit flavors)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51009-128-42	119 g in 1 TUBE		
2	NDC:51009-128-01	1 in 1 CARTON		
2		24.7 g in 1 TUBE		
3	NDC:51009-128-04	1 in 1 CARTON		
3		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	

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

Name	Address	ID/FEI	Business Operations
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Tom's of Maine, Inc.		052764354	MANUFACTURE
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Revised: 8/2010

Tom's of Maine, Inc.