

**SEA SALT ANTICAVITY SALT47 GENTLY SCRUBS AWAY SURFACE STAINS / FIGHTS BAD BREATH GERMS / STRENGTHENS ENAMEL- sodium fluoride paste, dentifrice  
Toms 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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**Sea Salt Anticavity Toothpaste SALT47  
gently scrubs away surface stains / fights bad breath germs / strengthens enamel**

***Drug Facts***

**Active ingredient**

Sodium fluoride 0.24% (0.15% 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, sorbitol, hydrated silica, xylitol, glycerin, sodium chloride, sodium lauryl sulfate, zinc citrate, natural flavor<sup>1</sup>, xanthan gum, carrageenan.

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

**Questions?**

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

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

4.7 OZ (133 g)

SINCE 1970  
Tom's®  
OF MAINE

natural  
with fluoride

SEA SALT

anticavity toothpaste

gently scrubs away surface stains

fightes bad breath germs

strengthens enamel

refreshing mint

with  
purified  
sea salt



*what's inside matters*  
We've been making safe and effective natural personal care products for you and your family since 1970! It all started when Tom and Kale Chappell moved to Maine. They couldn't find natural products for their children that supported their healthy lifestyle, so they made their own. This passion and pioneering spirit lives on at Tom's of Maine today. Our Stewardship Model, with standards for natural, sustainable, and responsible, guides every decision we make about our ingredients, processing, and packaging. To learn more about our Stewardship Model, and what "natural" means at Tom's of Maine visit [www.tomsofmaine.com](http://www.tomsofmaine.com).

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Kennebunk, ME 04043 U.S.A.

**What makes a product natural and good? At Tom's, it includes how we make it.**

No animal testing.

We share every ingredient, its purpose, and its source at [www.tomsofmaine.com](http://www.tomsofmaine.com).

LPS

Sustainable practices are a priority in every aspect of our business.

No artificial colors, flavors, fragrance, or preservatives.

We strive to maximize recycled content and recyclability of our packaging.

5% (12 days) of employee time to volunteering, 10% of profits to human and environmental goodness.



natural  
with fluoride  
SEA SALT  
anticavity toothpaste  
refreshing mint



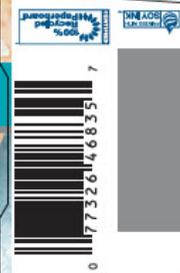
4.7 OZ (133 g)

natural  
with fluoride  
SEA SALT

anticavity toothpaste  
gently scrubs away surface stains  
fightes bad breath germs  
strengthens enamel  
refreshing mint



with  
purified  
sea salt



**Drug Facts**

**Active ingredient** Sodium fluoride (2.4% (0.15% 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 call (412) 350-6381 right away (Poison Control Center).

**Directions**

**Drug Facts (continued)**

adults and children 2 years of age and older

children 2 to 6 years

children under 2 years

brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician

use only a pea-sized amount and supervise child's brushing and rinsing (to minimize swallowing)

ask a dentist or physician

**Inactive ingredients** water, sorbitol, hydrated silica, xylitol, glycerin, sodium chloride, sodium lauryl sulfate, zinc citrate, natural flavor\*, xanthan gum, carrageenan.

**Questions?** 1-800-FOR-TOMS (1-800-367-0867)



**Goodness = Less in Landfills**  
Recycle Tom's of Maine\* and other packaging through the TerraCycle® collection program and earn rewards for your favorite nonprofit or school. Visit [www.tomsofmaine.com/terracycle](http://www.tomsofmaine.com/terracycle) to learn how.

GLUTEN-FREE



\*peppermint oil and other natural flavor

# SEA SALT ANTICAVITY SALT47 GENTLY SCRUBS AWAY SURFACE STAINS / FIGHTS BAD BREATH GERMS / STRENGTHENS ENAMEL

sodium fluoride paste, dentifrice

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51009-901
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Sodium Fluoride</b> (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	0.0024 g in 1g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Hydrated Silica</b> (UNII: Y6O7T4G8P9)	
<b>Xylitol</b> (UNII: VCQ006KQ1E)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Sodium Chloride</b> (UNII: 451W47IQ8X)	
<b>Sodium Lauryl Sulfate</b> (UNII: 368GB5141J)	
<b>Zinc Citrate</b> (UNII: K72I3DEX9B)	
<b>Peppermint Oil</b> (UNII: AV092KU4JH)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Carrageenan</b> (UNII: 5C69YCD2YJ)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	PEPPERMINT (Refreshing Mint)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51009-901-47	1 in 1 CARTON	11/12/2018	
1		133 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part355	11/12/2018	

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**Labeler** - Toms of Maine, Inc. (052764354)

**Establishment**

Name	Address	ID/FEI	Business Operations
Toms of Maine, Inc.		829517189	MANUFACTURE(51009-901)

Revised: 8/2019

Toms of Maine, Inc.