WHOLE CARE CINNAMON CLOVE- sodium monofluorophosphate paste, dentifrice WHOLE CARE PEPPERMINT- sodium monofluorophosphate paste, dentifrice WHOLE CARE SPEARMINT- sodium monofluorophosphate paste, dentifrice WHOLE CARE WINTERMINT- 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
WHOLE CARE
fluoride toothpaste

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

wears 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
	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, xylitol, *Chondrus crispus* (carrageenan), sodium lauryl sulfate, sodium bicarbonate, zinc citrate, *Cinnamomum cassia* (cinnamon) leaf oil and other natural flavors.

Questions?

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

PRINCIPAL DISPLAY PANEL - 133 g Carton

Since 1970 Tom's OF MAINETM

with fluoride | natural

WHOLE CARE®

fights cavities \mid whitening \mid fresh breath \mid helps fight tartar **fluoride toothpaste**

cinnamon clove

NET WT 4.7 OZ (133 g)



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



No animal testing or animal ingredients.

We share every **ingredient**.



its purpose, and its source at www.tomsofmaine.com. Sustainable practices are a priority in every aspect of

our business.



No artificial colors, flavors, fragrance, or preservatives.



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



Tom's of Malne™ Goodness Day



Learn more about how this tube reinforces our commitment to environmental stewardship at: www.tomsofmalne.com

Find us on:









with fluoride

de natural

WHOLE CARE

fights cavities | whitening | fresh breath | helps fight tartar fluoride toothpaste

cinnamon clove



NET WT 4.7 OZ (133 g)

Drug Facts	D
Active ingredient Purpose Sodium monofluorophosphate 0.76% (0.13% w/v fluoride ion) Anticavity	an
Use helps protect against cavities	dı
Warnings	dı
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).	Ir xy Cir
Directions	Q

Drug Facts (continued)

adults and children 2 years of age least twice a day, or as directed by a dentist or physician thildren 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, ylitol, Chondrus crispus (carrageenan), sodium lauryl sulfate, sodium bicarbonate, zinc citrate, innamomum cassis (cinnamon) leaf oil and other natural flavors.

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

Along with clinically-proven cavity protection from fluoride, this toothpaste whitens with naturally sourced silicas. This product also helps to freshen breath and prevent plaque and tartar buildup with regular brushing.

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Made in U.S.A.



PRINCIPAL DISPLAY PANEL - 133 g Carton

Since 1970 Tom's OF MAINETM

with fluoride | natural

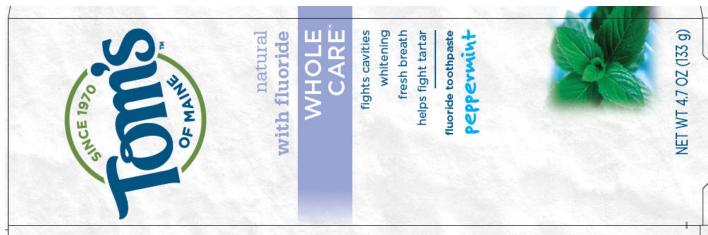
WHOLE CARE®

fights cavities | whitening | fresh breath | helps fight tartar

fluoride toothpaste

peppermint

NET WT 4.7 OZ (133 g)



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Tom's of Maine™ Goodness Day



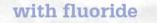
than our previous tube. Learn more about how this tube reinforces our commitment to environmental stewardship at: www.tomsofmalne.com

Find us on:



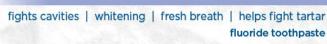






natural





eppermint



NET WT 4.7 OZ (133 g)

Drug Facts	Drug Facts (continued)	
Active ingredient Purpose Sodium monofluorophosphate 0.76% (0.13% w/v fluoride ion) Anticavity	adults and children 2 years of age and older	brush teeth thorough least twice a day, or a
Use helps protect against cavities	children 2 to 6 years	use only a pea-sized a brushing and rinsing (
Warnings	children under 2 years	ask a dentist or physic
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).	Inactive ingredients glycerin, water, calcium xylitol, Chondrus crispus (carrageenan), Mentha piperita (pep sodium bicarbonate, zinc citrate.	
Directions	Questions? 1-800-FOR-TO	OMS (1-800-367-866

hly, preferably after each meal or at as directed by a dentist or physician amount and supervise child's (to minimize swallowing) ician

m carbonate, hydrated silica, eppermint) oil, sodium lauryl sulfate,

67) M - F 8:30 a.m. - 5:30 p.m. ET

Along with clinically-proven cavity protection from fluoride, this toothpaste whitens with naturally sourced silicas. This product also helps to freshen breath and prevent plaque and tartar buildup with regular brushing.

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PRINCIPAL DISPLAY PANEL - 133 g Carton

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with fluoride | natural

WHOLE CARE®

fights cavities | whitening | fresh breath | helps fight tartar fluoride toothpaste

NET WT 4.7 OZ (133 g)



PRINCIPAL DISPLAY PANEL - 133 g Carton

Since 1970 Tom's OF MAINE™

with fluoride | natural

WHOLE CARE®

fights cavities | whitening | fresh breath | helps fight tartar

fluoride toothpaste

wintermint

NET WT 4.7 OZ (133 g)



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(I.P.S)

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Tom's of Malne™ Goodness Day

You asked - we listened!

This tube is easier to use than our previous tube. Learn more about how this tube reinforces our commitment to environmental stewardship at: www.tomsofmaine.com

Find us on







with fluoride

natural

fights cavities | whitening | fresh breath | helps fight tartar fluoride toothpaste

wintermint



NET WT 4.7 OZ (133 g)

Drug Facts Active ingredient **Purpose** rophosphate 0.76% (0.13% w/v fluoride ion) Use helps protect against cavities

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

Drug Facts (continued)

adults and children 2 years of age brush teeth thoroughly, preferably after each meal or at children 2 to 6 years

children under 2 years

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 glycerin, water, calcium carbonate, hydrated silica, xylitol Chondrus crispus (carrageenan), Gaultheria procumbers (wintergreen) leaf oil and other na flavors, sodium lauryl sulfate, sodium bicarbonate, zinc citrate.

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

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WHOLE CARE **CINNAMON CLOVE**

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51009-100

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Sodium monofluorophosphate (UNII: C810JCZ56Q) (fluoride ion - UNII:Q80 VPU408O)	So dium mo no fluo ro pho sphate	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)			
Xylitol (UNII: VCQ006KQ1E)			
Carrageenan (UNII: 5C69 YCD2YJ)			
Zinc citrate (UNII: K72I3DEX9B)			
Sodium Lauryl Sulfate (UNII: 368GB5141J)			
Cinnamon leaf oil (UNII: S92U8SQ71V)			
Clove oil (UNII: 578389 D6 D0)			
Clove stem oil (UNII: 9368 YZM9 M4)			

Product Characteristics		
Color	WHITE (off-white)	Score
Shape		Size
Flavor	CINNAMON (Cinnamon-Clove)	Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51009-100-47	1 in 1 CARTON		
1	133 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	02/14/2011	

WHOLE CARE PEPPERMINT

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-104

DENTAL

l	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength
	Sodium monofluorophosphate (UNII: C810JCZ56Q) (fluoride ion -UNII:Q80 VPU408O)	So dium mo no fluo ro pho sphate	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)		
Xylitol (UNII: VCQ006KQ1E)		
Carrageenan (UNII: 5C69 YCD2 YJ)		
Zinc citrate (UNII: K72I3DEX9B)		
Sodium Lauryl Sulfate (UNII: 368GB5141J)		
Peppermint Oil (UNII: AV092KU4JH)		

Product Characteristics			
Color	WHITE (off-white)	Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51009-104-47	1 in 1 CARTON		
1	133 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	02/14/2011	

WHOLE CARE SPEARMINT

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-105
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Sodium monofluorophosphate (UNII: C810JCZ56Q) (fluoride ion - UNII:Q80VPU408O)	Sodium monofluorophosphate	0.0076 g in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Calcium carbonate (UNII: H0 G9 379 FGK)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Xylitol (UNII: VCQ006KQ1E)	
Carrageenan (UNII: 5C69 YCD2YJ)	
Zinc citrate (UNII: K72I3DEX9B)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Spearmint Oil (UNII: C3M8 146 5G5)	
Peppermint Oil (UNII: AV092KU4JH)	

Product Characteristics			
Color WHITE (off-white) Score			
Shape		Size	
Flavor	SPEARMINT (Spearmint Ice)	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51009-105-47	1 in 1 CARTON		
1	133 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	02/14/2011	

WHOLE CARE WINTERMINT

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-106
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
Sodium monofluorophosp UNII:Q80VPU408O)	hate (UNII: C810JCZ56Q) (fluoride ion -	So dium mo no fluo ro pho sphate	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)		
Xylitol (UNII: VCQ006KQ1E)		
Carrageenan (UNII: 5C69YCD2YJ)		
Zinc citrate (UNII: K72I3DEX9B)		
Sodium Lauryl Sulfate (UNII: 368GB5141J)		
Methyl salicylate (UNII: LAV5U5022Y)		
Peppermint Oil (UNII: AV092KU4JH)		

Product Characteristics			
Color	WHITE (off-white)	Score	
Shape		Size	
Flavor	MINT (Wintermint)	Imprint Code	
Contains			

F	Packaging								
#	Item Code	Package Description	Marketing Start Date	Marketing End Date					
1	NDC:51009-106-47	1 in 1 CARTON							
1		133 g in 1 TUBE							

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC MONOGRAPH FINAL	part355	02/14/2011					

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

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

Revised: 2/2011 Tom's of Maine, Inc.