COLGATE OPTIC WHITE COOL MILD MINT-sodium monofluorophosphate paste, dentifrice

Mission Hills S.A de C.V

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.

Colgate[®] Optic White™ Cool Mild Mint Fluoride Toothpaste 4.0OZ

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76% (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 contact a Poison Control Center right away.

Directions

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	as a dentist or physician

Inactive ingredients

calcium pyrophosphate, propylene glycol, PEG/PPG 116/66 copolymer, PEG-12, glycerin, PVP, flavor, sodium lauryl sulfate, tetrasodium pyrophosphate, silica, hydrogen peroxide, sodium saccharin, phosphoric acid, sucralose, butylated hydroxytoluene, water

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 113 g Tube Carton

Colgate[®]

WHITER TEETH IN 1 WEEK
GOES BEYOND SURFACE STAIN REMOVAL TO DEEPLY WHITEN

ANTICAVITY FLUORIDE TOOTHPASTE | ENAMEL SAFE

 $\begin{array}{c} OPTIC \\ WHITE_{\Re} \end{array}$

NET WT 4.0 OZ (113 g) COOL MILD MINT



COLGATE OPTIC WHITE COOL MILD MINT

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65954-560
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
CALCIUM PYRO PHO SPHATE (UNII: X69 NU20 D19)	351.1 mg in 1 g	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PEG/PPG-116/66 COPOLYMER (UNII: JP0CK963E0)		
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
POVIDONE K15 (UNII: E54VE15114)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
SODIUM PYROPHO SPHATE (UNII: O352864B8Z)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
PHO SPHO RIC ACID (UNII: E4GA8884NN)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)		
WATER (UNII: 059QF0KO0R)		

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

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:65954-560-69	1 in 1 CARTON			
1		113 g in 1 TUBE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part355	0 1/0 1/20 12		

Labeler - Mission Hills S.A de C.V (812312122)

Revised: 10/2013 Mission Hills S.A de C.V