COLGATE KIDS WATERMELON FLAVOR- sodium fluoride gel, dentifrice Colgate-Palmolive Company

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 KIDS TOOTHPASTE MOUTHWASH WATERMELON FLAVOR

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 contact a Poison Control Center right away.

Directions

	brush teeth thoroughly, preferably
adults and children 2	after each meal or at least twice a
years of age and older	day, or as directed by a dentist or
	physician
	use only a pea sized amount and
children 2 to 6 years	supervise child's brushing and
	rinsing (to minimize swallowing)
children under 2 years	ask a dentist or physician

Inactive ingredients

sorbitol, water, glycerin, hydrated silica, PEG-12, sodium lauryl sulfate, tetrasodium pyrophosphate, cocamidopropyl betaine, sodium saccharin, flavor, xanthan gum, FD&C blue no. 1, FD&C yellow no. 5

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 130 g Bottle Label

2 in 1 Toothpaste & Mouthwash

Colgate[®] Fluoride Toothpaste

CLINICALLY PROVEN
Cavity and Enamel Protection

WATERMELON FLAVOR

NET WT 4.6 OZ (130 g) LIQUID GEL



COLGATE KIDS WATERMELON FLAVOR sodium fluoride gel, dentifrice Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:35000-905 Route of Administration DENTAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1.1 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
SORBITOL (UNII: 506T60A25R)	646.15 mg in 1 g	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
CO CAMIDO PRO PYL BETAINE (UNII: 50 CF30 11 KX)		
SODIUM PYROPHO SPHATE (UNII: O352864B8Z)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
XANTHAN GUM (UNII: TTV12P4NEE)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		

Product Characteristics			
Color	GREEN	Score	
Shape		Size	
Flavor	WATERMELON	Imprint Code	
Contains			

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:35000-905-81	130 g in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2011	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	07/26/2011	

Labeler - Colgate-Palmolive Company (001344381)

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