

COLGATE KIDS MILD BUBBLE FRUIT FLAVOR- sodium fluoride gel, 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® Kids Fluoride Toothpaste Mild Bubble Fruit® 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

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

sorbitol, water, hydrated silica, PEG-12, cellulose gum, sodium lauryl sulfate, flavor, sodium saccharin, mica, titanium dioxide, D&C yellow no. 10, FD&C blue no. 1

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 99 g Tube Label

Colgate®

Fluoride Toothpaste

CLINICALLY PROVEN
Cavity & Enamel Protection

ADA
Accepted
American
Dental
Association®

Kids

NET WT 3.5 OZ (99g)

Toothpaste

Mild BUBBLE FRUIT® FLAVOR



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Dental
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Kids

NET WT 3.5 OZ (99g) Toothpaste

Mild BUBBLE FRUIT[®] FLAVOR

TWIST OFF CAP AND REMOVE FOIL SEAL.
DO NOT USE IF SEAL IS NOT INTACT.

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Dist. by:
COLGATE-PALMOLIVE COMPANY
New York, NY 10022 **Made in Mexico**
www.colgate.com

"The ADA Council on Scientific Affairs' Acceptance of Colgate for Kids toothpaste is based on its finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed."



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480899

COLGATE KIDS MILD BUBBLE FRUIT FLAVOR

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65954-065
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	476 mg in 1 g
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65954-065-93	99 g in 1 TUBE; Type 0: Not a Combination Product	11/11/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	11/11/2016	

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