

COLGATE KIDS RYANS TOY WORLD ALCOHOL FREE ANTICAVITY RYANS BUBBLE FRUIT- sodium fluoride rinse

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 Ryan's Toy World™ Alcohol Free Anticavity Mouthwash Ryan's Bubble Fruit®

Drug Facts

Active ingredient

Sodium Fluoride 0.02% (0.01% w/v fluoride ion)

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warnings

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 6 years of age and older:

- use twice a day after brushing your teeth with a toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision

Children under 6 years of age: consult a dentist or doctor

Other information

Store at controlled room temperature 68 – 77° F (20 – 25°C)

Inactive ingredients

Water, Glycerin, Propylene Glycol, Sorbitol, Poloxamer 407, Poloxamer 338, Flavor, PEG-40 Hydrogenated Castor Oil, Phosphoric Acid, Sodium Saccharin, Disodium Phosphate, Potassium Sorbate, Cetylpyridinium Chloride, Sucralose, Blue 1.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 500 mL Bottle Label

ALCOHOL FREE

Colgate®

Anticavity Fluoride Rinse

KIDS

pocket.watch

RYAN'S

WORLD™

- ☐ Strengthens
Enamel
- ☐ Protects from
Cavities
- ☐ Cleans the
Whole Mouth*

16.9 FL OZ

(1.05 PT) 500 mL

RYAN'S BUBBLE FRUIT®

IMPORTANT: Read directions for proper use

P9933407

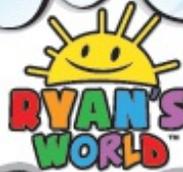
ALCOHOL FREE

Colgate®

Anticavity Fluoride Rinse

pocket watch

KIDS



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RYAN'S BUBBLE FRUIT®

P0853407

IMPORTANT: Read directions for proper use

Drug Facts

Active ingredient	Purpose
Sodium Fluoride 0.02% (0.01% w/v fluoride ion)	Anticavity

Use aids in the prevention of dental cavities

Warnings
Keep out of reach of children. If more

Drug Facts (continued)

Other information
Store at controlled room temperature
68 – 77° F (20 – 25°C)

Inactive ingredients
Water, Glycerin, Propylene Glycol,
Sorbitol, Poloxamer 407, Poloxamer 338,
Flavor, PEG-40 Hydrogenated Castor Oil,
Phosphoric Acid, Sodium Saccharin,



COLGATE KIDS RYANS TOY WORLD ALCOHOL FREE ANTICAVITY RYANS BUBBLE FRUIT

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-331
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLOXAMER 338 (UNII: F75JV2T505)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-331-84	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/28/2019	
2	NDC:35000-331-52	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/28/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	06/28/2019	

Labeler - Colgate-Palmolive Company (001344381)

Establishment

Name	Address	ID/FEI	Business Operations
Colgate-Palmolive		785047999	MANUFACTURE(35000-331)

Revised: 12/2019

Colgate-Palmolive Company