

**ACT KIDS ANTICAVITY FLUORIDE WILD WATERMELON- sodium fluoride rinse
Chattem, 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.

ACT Kids Anticavity Fluoride Rinse Watermelon

**ACT® Anticavity Wild Watermelon
Fluoride Rinse**

Active ingredient

Sodium Fluoride 0.05% (0.02% 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 Poison Control Center right away.

Directions

adults and children 6 years of age and older:

- use once a day after brushing your teeth with a toothpaste
- remove cap
- hold bottle upright and squeeze. Fill to FILL LINE
- pour out. Only the correct 10 milliliters dose will pour out
- vigorously swish 10 milliliters 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

- contains FD&C yellow no.5 (tartrazine) as a color additive
- do not use if safety seal is broken or missing

Inactive ingredients

calcium disodium EDTA, cetylpyridinium chloride, disodium phosphate, flavor, green 3, poloxamer 407, polysorbate 20, potassium sorbate, propylene glycol, sodium benzoate, sodium phosphate, sorbitol, sucralose, water, yellow 5 (309-023)

Principal Display Panel

ACT Kids
Anticavity Fluoride Rinse
Wild Watermelon
Sodium Fluoride 0.05%
16.9 fl oz (500 mL)

**#1 DENTIST RECOMMENDED
KID'S RINSE BRAND**

ACT

Kids

ANTICAVITY
FLUORIDE RINSE

wild water- melon

helps Prevent Cavities
Swish Away Particles
brushing may miss

alcohol free

Sodium Fluoride 0.05%
IMPORTANT Read
directions for proper use.

16.9 fl oz (500 mL) 0170108-01

ACT Kids FLUORIDE RINSE
alcohol free

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309-023
Learn more at www.ACToralcare.com
Bottle configuration is a trademark of Chattem, Inc. a Sandoz Company

CHATTEM Dist. by CHATTEM, INC.
P.O. Box 2219
Chattanooga, TN 37409
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† among mouth rinses

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ACT KIDS ANTICAVITY FLUORIDE WILD WATERMELON

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0938
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE CALCIUM DISODIUM ANHYDRO US (UNII: 8U5D034955)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SODIUM PHOSPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0K00R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	WATERMELON	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0938-1	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	12/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	12/01/2017	

Labeler - Chattem, Inc. (003336013)

