

**ACT ANTICAVITY FLUORIDE RINSE KIDS SCOOPY DOO- 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 Anticavity Fluoride Rinse Kids Scooby Doo

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
 Scooby-Doo! Kiwi Watermelon
 Sodium Fluoride 0.05%
 16.9 fl oz (500 mL)

ACT Kids FLUORIDE RINSE
alcohol free

Drug Facts

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Learn more at www.ACTFLUORIDE.com
 † among mouth rinses

Bottle configuration is a trademark of Signal Investment & Management Co.

SCOOBY-DOO: TM & © Hanna-Barbera (s12)

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 Dist. by CHATTEM, INC.
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 Chattanooga, TN 37409 USA
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#1 DENTIST RECOMMENDED
 FLUORIDE BRAND*
 alcohol free

NEW!

ACT Kids

Anticavity
 FLUORIDE RINSE

SCOOBY-DOO!
 KIWI WATERMELON

Sodium Fluoride 0.05%
 IMPORTANT: Read directions for proper use.

16.9 fl oz (500 mL)

SWISH AWAY PARTICLES
 brushing may miss

Helps PREVENT CAVITIES

ACT ANTICAVITY FLUORIDE RINSE KIDS SCOOBY DOO			
sodium fluoride rinse			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0934
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)	
CETYL PYRIDINIUM 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: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	KIWI	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0934-0	500 mL in 1 BOTTLE, DISPENSING		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	12/01/2012	

Labeler - Chattem, Inc. (003336013)**Establishment**

Name	Address	ID/FEI	Business Operations
Chattem		022072021	ANALYSIS(41167-0934) , LABEL(41167-0934) , MANUFACTURE(41167-0934) , PACK(41167-0934) ,

Revised: 3/2013

Chattem, Inc.