

**ACT KIDS ANTICAVITY FLUORIDE FRUIT PUNCH- 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 Fruit Punch

Drug Facts

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 a 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

- do not use if safety seal is broken or missing

Inactive ingredients

benzyl alcohol, blue 1, calcium disodium EDTA, cetylpyridinium chloride, disodium phosphate, flavor, poloxamer 407, polysorbate 20, potassium sorbate, propylene glycol, red 33, sodium benzoate, sodium

phosphate, sorbitol, sucralose, water

PRINCIPAL DISPLAY PANEL

Act Kids

Anticavity Fluoride

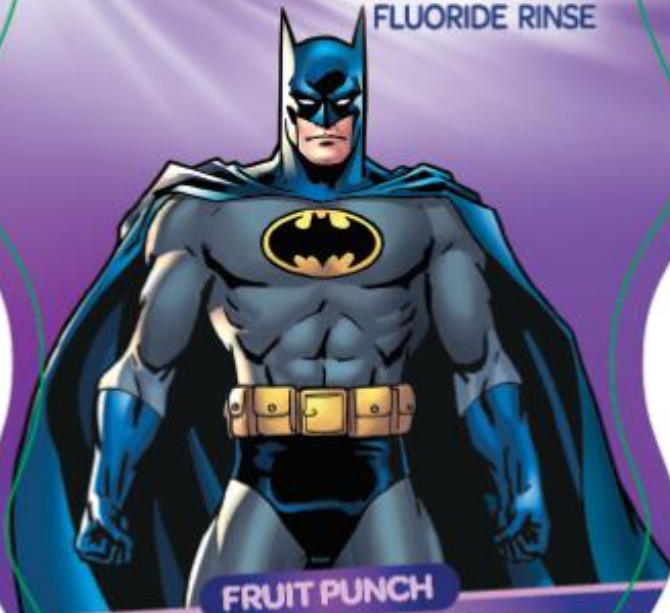
16.9 fl oz (500 mL)

#1 DENTIST RECOMMENDED
KID'S RINSE BRAND*

ACT[®]

Kids

ANTICAVITY
FLUORIDE RINSE



FRUIT PUNCH

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)

0070952-01



ACT[®] Anticavity Kids FLUORIDE RINSE

alcohol free

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Learn more at www.ACToralcare.com

Bottle configuration is a trademark of Chattem, Inc., a Sanofi Company



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P.O. Box 2219, Chattanooga, TN 37409
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† among mouth rinses 0070953-01



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ACT KIDS ANTICAVITY FLUORIDE FRUIT PUNCH

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0936
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	FRUIT PUNCH	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0936-5	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	12/16/2015	

Labeler - Chattem, Inc. (003336013)

