

ACT RESTORING ANTICAVITY FLUORIDE COOL MINT- sodium fluoride mouthwash
Chattem, Inc.

ACT Restoring Anticavity Fluoride Mouthwash Cool Mint

Drug Facts

Active ingredients

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
- pour 10 milliliters (10 mL mark on inside of cap); do not fill above 10 mL mark
- 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

water, alcohol (11%), sorbitol, poloxamer 407, propylene glycol, sodium benzoate, flavor, sodium phosphate, polysorbate 20, sodium saccharin, cetylpyridinium chloride, disodium phosphate, calcium disodium EDTA, blue 1 (245-167)

www.actfluoride.com

PRINCIPAL DISPLAY PANEL

**#1 DENTIST RECOMMENDED
FLUORIDE BRAND**

ACT

1X Daily

RESTORING

ANTICAVITY FLUORIDE MOUTHWASH

COOL MINT

18 fl oz (532 mL)



ACT RESTORING ANTICAVITY FLUORIDE COOL MINT

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0957
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0957-5	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	02/01/2006	

Labeler - Chattem, Inc. (003336013)

Establishment

Name	Address	ID/FEI	Business Operations
CHATTEM, INC.		832973031	label(41167-0957) , manufacture(41167-0957) , pack(41167-0957)

