

ALCOHOL-FREE ANTICAVITY- sodium fluoride liquid
TOPCO Associates LLC

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.

Top Care Anticavity Fluoride Rinse
482.001/482AB

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 daily after brushing your teeth with a toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute 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

Inactive ingredients

water, glycerin, cetylpyridinium chloride, flavor, sodium saccharin, phosphoric acid, sodium benzoate, sucralose, poloxamer 407, benzoic acid, disodium phosphate, propylene glycol, red 33, green 3

Sealed with printed neckband for your protection

Topcare everyday

- Helps strengthen enamel
- Helps prevent cavities
- Kills bad breath germs
- Freshens breath

This rinse may cause temporary staining to the surface of teeth. This is not harmful, and adequate brushing may prevent its occurrence.

*This product is not manufactured or distributed by Procter + Gamble, distributor of Crest Pro-Health Complete Anticavity Fluoride Rinse

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

1-888-423-0139 topcare@topco.com www.topcarebrand.com

principal display panel

Compare to Crest Pro-Health Advanced Anticavity Fluoride Mouthwash*

Topcare everyday

Alcohol free Fluoride Anticavity Mouthwash

Violet mint

- Helps strengthen enamel
- Helps prevent cavities
- Helps keep mouth feeling clean
- Kills bad breath germs
- Freshens breath

IMPORTANT: read directions for proper use.

33.8 FL OZ (1 QT 1.8 FL OZ) 1 L



ALCOHOL-FREE ANTICAVITY

sodium fluoride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-482
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.219 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	

GLYCERIN (UNII: PDC6A3C0OX)
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
PHOSPHORIC ACID (UNII: E4GA8884NN)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SUCRALOSE (UNII: 96K6UQ3ZD4)
POLOXAMER 407 (UNII: TUF2IWW3M2)
BENZOIC ACID (UNII: 8SKN0B0MIM)
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-482-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/19/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/19/2013	

Labeler - TOPCO Associates LLC (006935977)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(36800-482)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(36800-482)