

ALCOHOL-FREE ANTICAVITY- sodium fluoride liquid
Liberty Procurement, 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.

Alcohol Free Fluoride Violet Mint Mouthwash
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

for this product

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

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

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

ALCOHOL FREE

COREVALUES

Anticavity MOUTWASH FLUORIDE RINSE

Distributed by

Liberty Procurement, Inc

650 Liberty Ave

Union, NJ 07083 USA

principal display panel

SEALED WITH

PRINTED NECK BAND FOR YOUR PROTECTION

ALCOHOL FREE

COREVALUES

*Compare to the active ingredient in Crest Pro-Health Complete

Anticavity

MOUTHWASH

FLUORIDE RINSE

- Helps prevent cavities
- Helps make enamel stronger
- Helps clean the entire mouth
- Helps freshen breath
- Helps kill germs that cause bad breath

Violet Mint

IMPORTANT: Read directions for proper use.

1L (33.8 FL OZ)



ALCOHOL-FREE ANTICAVITY

sodium fluoride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-482
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.2 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:63940-482-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/28/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/28/2016	

Labeler - Liberty Procurement, Inc (804085293)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(63940-482)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(63940-482)