

**ALCOHOL-FREE ANTICAVITY- sodium fluoride liquid**  
**Retail Business Services, 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.*

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**Alcohol Free Fluoride Violet Mint Mouthwash**  
**482.001/482AB**

**TEP**

**SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION**

**Active ingredients**

Sodium fluoride 0.02% (0.0 1% 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 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

### **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

### **Claims**

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

### **Disclaimer**

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

\*\*This product is not intended to replace brushing or flossing.

### **Adverse reaction**

DISTRIBUTED BY: FODHOLD U.S.A., LLC

LANDOVER, MD 20785

1-877-846-9949

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Quality guaranteed or your money back.

### **Principal display panel**

CAREONE

Compare to the Active Ingredient in Crest Pro-Health™ Advanced Anticavity Fluoride Mouthwash\*

ALCOHOL FREE

FLUORIDE MOUTHWASH

ANTICAVITY

FLUORIDE RINSE

VIOLET MINT FLAVOR

KILLS BAD BREATH GERMS

HELPS PREVENT CAVITIES

HELPS STRENGTHEN ENAMEL

CLEANS TEETH\*\*

FRESHENS BREATH

IMPORTANT: Read directions for proper use

33.8 FL OZ (1.05 QT) 1L



## ALCOHOL-FREE ANTICAVITY

sodium fluoride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-482
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 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:72476-482-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/03/2013	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/01/2013	

**Labeler** - Retail Business Services, LLC (967989935)

**Registrant** - Vi-Jon, LLC (790752542)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72476-482)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(72476-482)