

**ALCOHOL-FREE ANTICAVITY- sodium fluoride liquid
H-E-B**

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

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

Questions?

Call 1-888-593-0593

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

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

H-E-B

Violet Mint

ALCOHOL FREE

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

MADE WITH PRIDE AND CARE FOR H-E-B, SAN ANTONIO, TX, 78204

100% GUARANTEE PROMISE

If you aren't completely pleased with this product, we'll be happy to replace it or refund your money. You have our word on it.

Principal Panel Display

Compare to Crest Pro-Health Rinse

H-E-B

Violet Mint

ALCOHOL FREE

ANTICAVITY MOUTH RINSE WITH FLUORIDE

- Helps prevent cavities
- Helps fight germs that cause bad breath
- Freshens breath with no alcohol burn

IMPORTANT: Read directions for proper use.

33.8 FL OZ (1 QT) 1 L

*Compare to Crest®
Pro-Health™ Rinse



Violet Mint

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FREE**

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L0015826FA

ALCOHOL-FREE ANTICAVITY

sodium fluoride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-942
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (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)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
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:37808-942-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/17/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/17/2017	

Labeler - H-E-B (007924756)**Registrant** - Vi-Jon, LLC (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(37808-942)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(37808-942)

