#### ORAL ANTIVAVITY- sodium fluoride mouthwash Kroger Co

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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#### Krogers, 576.001/576AC-AD

#### claims

Kroger FROM OUR FAMILY TO YOURS Refreshing Mint ALCOHOL FREE FLUORIDE MOUTHWASH

#### Active ingredient

Sodium fluoride 0.0219% (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 a day 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 witout supervision
- children under 6 years of age: consult a dentist or doctor

#### Inactive ingredients

water, glycerin, flavor, cetlpyridinium chloride, poloxamer 407, phosphoric acid, methylparaben, sodium saccharin, propylparaben, propylene glycol, disodium phosphate, blue 1

#### **Questions or comments?**

1-800-632-6900

#### Claims

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

#### Disclaimer

CREST IS A REGISTERED TRADEMARK OF THE PROCTER & GAMBLE COMPANY, CINCINNATI, OHIO 45202. THE PROCTER & GAMBLE COMPANY IS NOT AFFILIATED WITH THE KROGER CO. OR THIS PRODUCT.

#### **Adverse Reactions**

DISTRIBUTED BY THE KROGER CO., OHIO 452020

QUALITY GUARANTEE

www.kroger.com

#### principal display panel

COMPARE TO the active ingredient of CREST PRO-HEALTH COMPLETE ANTICAVITY FLUORIDE RINSE See Back Label Kroger Refreshing Mint

#### ALCOHOL-FREE

FLUORIDE MOUTHWASH

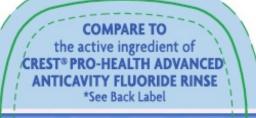
#### ANTICAVITY FLUORIDE RINSE

IMPORTANT: read directions for proper use.

- Helps Prevent Cavities
- Helps Make Enamel Stronger
- Helps Clean the Entire Mouth
- Helps Kill Germs that Cause Bad Breath
- Helps Freshen Breath
- No Alcohol Burn

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

33.8 FL OZ (1 L)



# **Refreshing Mint**

## ALCOHOL-FREE FLUORIDE MOUTHWASH

### ANTICAVITY FLUORIDE RINSE

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SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION LOOI4832FB

33.8 FL OZ (1 L)

**ORAL ANTIVAVITY** 

Strengtn       Strengtn         Inactive Ingredients       FLUORIDE ION -       FLUORIDE ION       10.41 mg in 12         Inactive Ingredients         Strengt         WATER (UNII: 059QF0K00R)         GLYCERIN (UNII: 059QF0K00R)         GLYCERIN (UNII: 059QF0K00R)         GLYCERIN (UNII: DOGA3C00X)         CETYLPYRIDINIUM CHLORIDE (UNII: D90M4SK49P)         POLOXAMER 407 (UNII: TUF2I/W3M2)         POSPHORIC ACID (UNII: E4GA8884NN)         METHYLPARABEN (UNII: SBZUX40TY)         PROPYLPARABEN (UNII: SBZUX40TY)         PROPYLENE GLYCOL (UNII: B8ZUX40TY)         PROPYLENE GLYCOL (UNII: B8ZUX40TY)         PROPYLENE GLYCOL (UNII: B8ZUX40TY)         PROPYLENE GLYCOL (UNII: B8ZUX40TY)         PROPYLENE GLYCOL (UNII: BABASIC, ANHYDROUS (UNII: 22AD053M6F)         FD&C BLUE NO. 1 (UNII: H3R47K3TBD)         PACKaging         Marketing Information	sodium fluoride	mouthwash							
Ingredient/Active Moiety         Active Ingredient/Active Moiety         Basis of Strength         Strength         Strength         Strength         Strength         Strength         Strength         Strength         Strength         Ingredients         Strength         Ingredient Name       Strength	Product Info	rmation							
ORAL         Active Ingredient/Active Moiety         Active Ingredient Name       Basis of Strength       Strength         SoDIUM FLUORIDE (UMI: 8Z YQ1474W7) (FLUORIDE ION -       FLUORIDE ION       Ingredient Name       Strength         SoDIUM FLUORIDE (UMI: 8Z YQ1474W7) (FLUORIDE ION -       FLUORIDE ION       Ingredient Name       Strengt         WATER (UMII: 0809QF0K00R)       Glycernin (UMII: PDC6A3C00X)         GLYCERIN (UMII: PDC0A3C00X)       Strengt         POLOXAMER 407 (UMII: PD2/WBM2)       POPOLOXAMER 407 (UMII: 21/W3M2)         POPOLOXAMER 407 (UMII: 21/W3M2)       POPOPYLARABEN (UMII: A218C7H19T)         SACCHARIN SODIUM (UMII: SB2/VA0TY)       PROPYLARABEN (UMII: A218C7H19T)         SACCHARIN SODIUM (UMII: SB2/VA0TY)       PROPYLARABEN (UMII: A218C7H19T)         SACCHARIN SODIUM (UMII: SB2/VA0TY)       PROPYLARABEN (UMII: A218C7H19T) <th colsp<="" th=""><th>Product Type</th><th></th><th>HUMAN OTC DRUG</th><th>ltem Cod</th><th>le (Source)</th><th>NDC:30142-576</th></th>	<th>Product Type</th> <th></th> <th>HUMAN OTC DRUG</th> <th>ltem Cod</th> <th>le (Source)</th> <th>NDC:30142-576</th>	Product Type		HUMAN OTC DRUG	ltem Cod	le (Source)	NDC:30142-576		
Active Ingredient/Active Moiety Ingredient Name Basis of Strength SoDIUM FLUORIDE (UNII: 8Z YQ1474W7) (FLUORIDE ION - FLUORIDE ION 10.41 mg in 3 10.41 mg in		istration	ORAL						
Ingredient Name         Basis of Strength         Strength           SODIUM FLUORIDE (UNII: 82YQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)         FLUORIDE ION         10.41 mg in 3           Inactive Ingredients         Ingredient Name         Strengt           WATER (UNII: 059QF0K00R)         Ingredient Name         Strengt           WATER (UNII: 059QF0K00R)         Ingredient Name         Strengt           WATER (UNII: 059QF0K00R)         Ingredient Name         Strengt           POLOXAMER 407 (UNII: TUF2IW08/2)         POLOXAMER 407 (UNII: TUF2IW08/2)         POLOXAMER 407 (UNII: A382C710)           PHOSPHORIC ACID (UNII: E4GA8884NN)         Ingredient Name         Ingredient Name           METHYLPARABEN (UNII: 28X25C10H)         PROPYLPARABEN (UNII: 28X25C10H)         PROPYLPARABEN (UNII: 28X25C10H)           PROPYLENE GLYCOL (UNII: BEASIC, ANHYDROUS (UNII: 22AD053M6F)         Ingredient Name         Ingredient Name           PACKaging         Package Description         Marketing Start         Marketing E Date           1         INDC:30142- 576-86         1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a 576-86         02/06/2015         Date           Marketing Information         Marketing Category         Application Number or Monograph         Marketing Start         Marketing E Date									
Ingredient Name       Strength       Strength         SODUM FLUORIDE (UNII: 82YQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)       FLUORIDE ION       10.41 mg in 1         Inactive Ingredients       Ingredient Name       Strength         Inactive Ingredients       Strength       Strength         Inactive Ingredients       Ingredient Name       Strength         WATER (UNII: 059QF0K00R)       Ingredient Name       Strength         GlyCERIN (UNII: 059QF0K00R)       Ingredient Name       Strength         GlyCERIN (UNII: 059QF0K00R)       Ingredient Name       Ingredient Name         VATER (UNII: 059QF0K00R)       Ingredient Name       Ingredient Name         GlyCERIN (UNII: 059QF0K00R)       Ingredient Name       Ingredient Name         FOPULAMER 407 (UNII: TUF2IVW3M2)       Ingredient Name       Ingredient Name         PROPYLPARABEN (UNII: 284282019)       Ingredient Name       Ingredient Name         Strength       Ingredient Name       Ingredient Name         Strength       Ingredient Statt       Ingredient Name         Strength       Ingredient Name       Ingredient Name         Strength       Ingredient Name       Ingredient Name         Strength       Ingredient Statt       Ingredient Name         Strength       Ingredient Statt	Active Ingred	ient/Active	Moiety						
UNII:Q80VPU4080) Inclusion Provide Ion Pro		Ingred	ient Name			Strength			
Ingredient NameStrengtWATER (UNII: 059QF0K00R) GLYCERIN (UNII: PDC6A3C00X)GLYCERIN (UNII: PDC6A3C00X) </td <td></td> <td>DE (UNII: 8ZYQ14</td> <td>74W7) (FLUORIDE ION -</td> <td></td> <td>FLUORIDE ION</td> <td>10.41 mg in 1 m</td>		DE (UNII: 8ZYQ14	74W7) (FLUORIDE ION -		FLUORIDE ION	10.41 mg in 1 m			
Ingredient NameStrengtWATER (UNII: 059QF0K00R) GLYCERIN (UNII: PDC6A3C00X) </td <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>									
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GLYCERIN (UNII: PDC6A3C00X)       Image: Start Stard Start Start Start Start Start Start Sta		Strength							
CETYLPYRIDINIUM CHLORIDE (UNII: D90M4SK49P)         POLOXAMER 407 (UNII: TUF2IVW3M2)         PHOSPHORIC ACID (UNII: E4GA8884NN)         METHYLPARABEN (UNII: A208C7H19T)         SACCHARIN SODIUM (UNII: SB8ZUX40TY)         POPYLPARABEN (UNII: Z81X2SC10H)         PROPYLENE GLYCOL (UNII: 6DC9Q167V3)         SODIUM PHOSPHATE, D1BASIC, ANHYDROUS (UNII: 22AD053M6F)         FD&C BLUE NO. 1 (UNII: H3R47K3TBD)         Marketing Start D000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product         NDC:30142- S76-86         Marketing Information         Marketing Start D1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product         Marketing Start D1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	WATER (UNII: 0590	QF0KO0R)							
POLOXAMER 407 (UNII: TUF2IVW3M2)       Image: Combination Product	GLYCERIN (UNII: P	DC6A3C0OX)							
PHOSPHORIC ACID (UNII: E4GA8884NN)       Image: Sector of the sector of th	CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)								
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SACCHARIN SODIUM (UNII: SB8Z UX40TY)         Image: Sodium (UNII: SB8Z UX40TY)         PROPYLPARABEN (UNII: Z8IX2SC10H)         PROPYLENE GLYCOL (UNII: 6DC9Q167V3)         Sodium PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22AD053M6F)         FD&C BLUE NO. 1 (UNII: H3R47K3TBD)         Marketing Start Diate         Package Description         Marketing Start       Date         1       NDC:30142- 576-86       1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       02/06/2015         Marketing Start Diate         Marketing Start Diate         Marketing Start Diate									
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PROPYLENE GLYCOL (UNII: 6DC9Q167V3)       Image: constraint of the state of the st									
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FJ&C BLUE NO. 1 (UNII: H3R47K3TBD)     Packaging   # Item Code   Package Description Marketing Start Date   Date   1   NDC:30142- 576-86   1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product   O2/06/2015   O2/06/2015   Marketing Endertain Application Number or Monograph Marketing Start Date   Marketing Endertain Marketing Endertain Application Number or Monograph Date									
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#       Item Code       Package Description       Marketing Start Date       Marketing E Date         1       NDC:30142- 576-86       1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       02/06/2015       02/06/2015         Marketing Treation Product         Marketing Start Date         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing Er Date	FD&C BLUE NO. 1	<b>L</b> (UNII: H3R47K3	TBD)						
#       Item Code       Package Description       Date       Date         1       NDC:30142- 576-86       1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       02/06/2015       02/06/2015         Marketing Information       Marketing Start Date       Marketing Start Date       Marketing Er Date	Packaging								
S76-86       Combination Product       02/06/2013         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing Er Date	# Item Code	Pa	ackage Description						
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Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing Er Date									
Category Citation Date Date	Marketing	Informat	ion						
OTC monograph final part355 02/06/2015		Applicat		graph		Marketing End Date			
	OTC monograph fir	nal part355		0	2/06/2015				

Labeler - Kroger Co (006999528)

Registrant - Vi-Jon, LLC (790752542)

#### Establishment

Name	Address	ID/FEI	<b>Business Operations</b>				
Vi-Jon, LLC		790752542	manufacture(30142-576)				
Establishment							
Name	Address	ID/FEI	<b>Business Operations</b>				
Vi-Jon, LLC		088520668	manufacture(30142-576)				

Revised: 4/2022

Kroger Co