HYVEE COMPLETE CARE FRESH MINT- sodium fluoride liquid
HYVEE 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.

DRUG FACTS

Active Ingredient

Sodium Fluoride 0.02% (0.01% w/v Fluoride ion)

Purpose

Antigingivitis/Antiplaque

Uses

to help reduce and prevent
- plaque
- gingivitis

Warnings

Do not use in children under 12 years of age

Keep out of reach of children

If more than used for rinsing is accidentally ingested, get medical help or contact a Poison Control Center immediately

Directions
- Rinse full strength for 30 seconds with 20 mL (2/3 fluid ounce or 4 teaspoonfuls) morning and night
- Do not swallow

Other information
- Store at room temperature
- Cold weather may cloud this product. Its antiseptic properties are not affected.

Inactive ingredients

Water (Aqua), Sorbitol, Alcohol (21.6%), Poloxamer 407, Sodium Lauryl Sulfate, Eucalyptol, Flavor, Methyl Salicylate, Thymol, Phosphoric Acid, Sucralose, Menthol, Disodium Phosphate, Red 40 (CI 16035), Blue 1 (CI 42090).

Questions or comments?

1-800-289-8343

Label Copy

HYVEE COMPLETE CARE FRESH MINT

sodium fluoride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42507-552
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.2 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
ALCOHOL (UNII: 3K9958V90M)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
EUCALYPTOL (UNII: RV6J6604TK)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
THYMOL (UNII: 3J50XA376E)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-552-33	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/12/2013	

Labeler - HYVEE INC. (006925671)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(42507-552)

Revised: 11/2015 HYVEE INC.