

**HYVEE HEALTH COOL BLUE SUGAR FREE- eucalyptol, menthol, methyl salicylate,
thymol mouthwash
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 ingredients

Eucalyptol 0.092%, Menthol 0.042%, Methyl Salicylate 0.060%, Thymol 0.064%

Purpose

Antiplaque/Antigingivitis

Uses

to help reduce and prevent plaque and gingivitis.

Warnings

Do not use for children under 12 years of age.

Keep out of reach of children.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center immediately (1-800-222-1222).

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), Alcohol, Poloxamer 407, Flavor, Benzoic Acid, Sodium Benzoate, Sodium Saccharin, Sucralose, Green 3 (CI 42053).

Label Copy

HyVee. health

Sugar Free Mouthwash

Cool Blue

Kills Germs & Fights Gum Disease



33.8 FL OZ (1 L)

06-21251

Drug Facts

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DO NOT USE IF BAND AROUND CAP IS BROKEN OR MISSING. **TO OPEN:** SQUEEZE SMOOTH AREAS ON CAP AND TURN. **TO CLOSE:** TURN CAP UNTIL IT LOCKS.

DISTRIBUTED BY HY-VEE, INC.
WEST DES MOINES, IA 50266

MADE IN CANADA

SATISFACTION GUARANTEED
CALL 1-800-289-8343
www.hy-vee.com



06-21252

HYVEE HEALTH COOL BLUE SUGAR FREE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-561
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 mg in 1 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.60 mg in 1 mL
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
POLOXAMER 124 (UNII: 1S66E28KXA)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-561-33	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 not final	part356	03/08/2016	

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(42507-561)

Revised: 3/2016

HYVEE INC