### KROGER COOL MINT BOOST MOUTH- eucalyptol, menthol, methyl salicylate, thymol rinse The Kroger Company

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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#### **Drug Facts**

# Active ingredients

Eucalyptol 0.92%, Menthol 0.042%, Methyl Salicylate 0.060%, Thymol 0.064%

### Purpose

Antigingivitis, Antiplaque

# Uses

helps control plaque that leads to gingivitis, an early form of gum disease.

### Warnings

### Stop use and ask a dentist if

- gingivitis, bleeding, or redness persists for more than 2 weeks.
- you have painful or swollen gums, pus from the gum line, loose teeth, increasing space between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

Keep out of reach of children under 6 years of age.

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

# Directions

Adults and children 12 years of age and older: vigorously swish 20 milliliters of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow

Children 6 years to under 12 years of age: supervise use.

Children under 6 years of age: do not use

# Other information

- this rinse is not intended to replace brushing or flossing.
- store at room temperature.
- cold weather may cloud this product. Its antiseptic properties are not affected.

# Inactive ingredients

Water (Aqua), Alcohol (21.6%), Poloxamer 407, Flavor, Benzoic Acid, Sodium Saccharin, Sodium Benzoate, Sucralose, Green 3 (CI 42053).

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

# Label Copy

SUGAR-FREE	Drug Facts Active ingredients Eucalyptol 0.092%, Menthol 0.042% Methyl Salicylate 0.060%, Thymol 0	Purpose Antigingivitis, Antiplagu .064%		
	Use helps control plaque that leads t	Use helps control plaque that leads to gingivitis, an early form of gum disease.		
	Warnings			
Midden	Stop use and ask a dentist if III gingivitis, bleeding, or redness persists for more than 2 weeks III you have painful or swollen gums, pus from the gum line, loose teeth, increasing space between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease. Keep out of reach of children under 6 years of age. If more than used for rinsing is accidentally ingested, get medical help or contact a Poison Control Center immediately.			
	Directions			
Cool Mint Boost	Adults and children 12 years of age and older	vigorously swish 20 milliliters of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow.		
	Children 6 years to under 12 years of age	supervise use.		
MOUTH RINSE	Children under 6 years of age	do not use.		
MOUTH KINSE	Other information  This rise is not intended to replace brushing or flossing. Store at room temperature.  Cold weather may cloud this product. Its antiseptic properties are not affected.			
LONG-LASTING COOLING EFFECT - UP TO 3 HOURS AFTER USE	Inactive ingredients Water (Aqua), Acohol (21.6%), Polonamer 407, Flavor, Benzoic Acid, Sodium Saccharin, Sodium Benzoate, Sucraiose, Green 3 (Cl 42053).			
Kills Germs That Cause Bad Breath,	Questions or comments? 1-800-632-6900			
Plaque and Gingivitis SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION 33.8 FL OZ (1 L)	DISTRIBUTED BY THE KROGE CINCINNATI, OHIO 4520 Made in Canada QUALITY GUARANTEE 800-632-6900 • www.kroger	R CO.		

# **KROGER COOL MINT BOOST MOUTH**

eucalyptol, menthol, methyl salicylate, thymol rinse

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-978
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:0414PZ4LPZ)	METHYL SALICYLATE	0.6 mg in 1 mL			
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64  mg  in  1  mL			

# Inactive IngredientsIngredient NameStrengthWATER (UNII: 059QF0K00R)ALCOHOL (UNII: 3K9958V90M)POLOXAMER 407 (UNII: TUF2IVW3M2)BENZOIC ACID (UNII: 8SKN0B0MIM)SACCHARIN SODIUM (UNII: SB8ZUX40TY)SODIUM BENZOATE (UNII: 0J245FE5EU)

SUCRALOSE (UNII: 96K6UQ3ZD4)         FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)         Packaging         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:30142-978-       1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       02/14/2018       Marketing Information						
Packaging#Item CodePackage DescriptionMarketing Start DateMarketing End Date1NDC:30142-978- 331000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product02/14/2018	st	JCRALOSE (UNII: S	96K6l	JQ3ZD4)		
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#     Item Code     Package Description       Date     Date       1     NDC:30142-978- 33     1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product     02/14/2018	ш	Item Code			<b>Marketing Start</b>	Marketing End
1         33         Product         02/14/2018	#	Item Code		Package Description	-	-
Marketing Information		, , , , ,		02/14/2018		
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OTC monograph not final part356 02/14/2018	07	ГС monograph not	final	part356	02/14/2018	

Labeler - The Kroger Company (006999528)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Apollo Health and Beauty Care Inc.		201901209	manufacture(30142-978)

Revised: 2/2018

The Kroger Company