# LIP BALM ROOT BEER FLAVORED- spf 15 lipstick Webb Business Promotions

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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## SPF 15 Lip Balm Root Beer Flavored

## Purpose

## **Purpose**

Sun Screen

# **Drug Facts**

Octinoxate 3.6%

Octisalate 2.5%

Benzophenone 1.5%

# **Inactive Ingredients**

Hydrogenated Soybean Oil, Sunflower Oil, White Beeswax Pastilles, Cocoa Butter, Shea Butter, Vitamin E, Aloe Vera Gel, Root Beer Flavoring.

#### Warnings

- **Skin Cancer/Skin Aging Alert:** Spending too much time in the sun increases your risk of skin cancer and early skin aging. This product has been shown to only help prevent sunburn, not skin cancer or early skin aging.
- For external use only.
- **Do not use** on damaged or broken skin.
- **Stop use and ask doctor** if rash occurs.
- When using this product keep out of eyes.
- **Keep out of reach of children.** If swallowed get medical help or contact posion control center right away.

#### Directions

- Apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply every 2 hours
- Children under 6 months : Ask a doctor

## **Storage and Handling Information**

Protect this product from excessive heat and direct sun

#### ROOT BEER FLAVORED SPF 15 NATURAL BEESWAX LIP BALM

## ROOT BEER FLAVORED SPF 15 NATURAL BEESWAX LIP BALM

DRUG FACTS			Net Wt. : 0.15 oz / 4.2 g	
Active Ingredie	nts	Purpose	Inactive Ingredients: Hydrogenated	
Octinoxate Octyl Salicylate Oxybenzone	3.6% 2.5% 1.5%		Soybean Oil, Sunflower Oil, White Bees Wax Pastilles, Cocoa Butter, Shea Butter, Vitamin E, Aloe Vera	
Uses Helps prev	ent sunbu	irn	Gel, Root beer Flavoring.	

#### Warnings

- Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
- For external use only.
- Do not use on damaged or broken skin.
- Stop use and ask a doctor if rash occurs.
- When using this product keep out of eyes. Rinse with water to remove.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

- Apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months: Ask a doctor

**Other Information:** Protect this product from excessive heat and direct sun

Dist. by: Webb Eagan, MN 55121 Made in USA.

## LIP BALM ROOT BEER FLAVORED

spf 15 lipstick

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70445-235	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.6 g in 1 g		
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	2.5 g in 1 g		
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1.5 g in 1 g		

Inactive Ingredients			
Ingredient Name	Strength		
HYDROGENATED SO YBEAN O IL (UNII: A2M9 1M9 18 C)			
COCOA BUTTER (UNII: 512OYT1CRR)			
SHEA BUTTER (UNII: K49 155WL9 Y)			
ALOE VERA LEAF (UNII: ZY81Z83H0 X)			

.ALPHATO COPHEROL (UNII: H4N855PNZ1)	
WHITE WAX (UNII: 7G1J5DA97F)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor	ROOT BEER	Imprint Code		
Contains				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:70445-235-01	5 g in 1 TUBE; Type 0: Not a Combination Product	09/11/2009		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	0 1/0 1/20 0 9	

# **Labeler** - Webb Business Promotions (154445647)

Establishment				
Name	Address	ID/FEI	Business Operations	
Webb Business Promotions		154445647	manufacture(70445-235)	

Revised: 3/2017 Webb Business Promotions