

LIP BALM BOURBON 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.

SPF 15 Lip Balm Bourbon 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, Bubble Gum 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 poison 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

BOURBON FLAVORED SPF 15 NATURAL BEESWAX LIP BALM

**BOURBON FLAVORED
SPF 15 NATURAL BEESWAX LIP BALM**

DRUG FACTS		Net Wt. : 0.15 oz / 4.2 g
Active Ingredients	Purpose	Inactive Ingredients: Hydrogenated Soybean Oil, Sunflower Oil, White Bees Wax Pastilles, Cocoa Butter, Shea Butter, Vitamin E, Aloe Vera Gel, Bourbon Flavoring.
Octinoxate 3.6%	Sunscreen	
Octyl Salicylate 2.5%		
Oxybenzone 1.5%		
Uses	Helps prevent sunburn	
Warnings		
<ul style="list-style-type: none"> • 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		
<ul style="list-style-type: none"> • 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 BOURBON FLAVORED

spf 15 lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70445-267
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: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	1.5 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)	
COCOA BUTTER (UNII: 512OYT1CRR)	
SHEA BUTTER (UNII: K49155WL9Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
WHITE WAX (UNII: 7G1J5DA97F)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70445-267-01	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	01/01/2009	

Labeler - Webb Business Promotions (154445647)

Establishment

Name	Address	ID/FEI	Business Operations
Webb Business Promotions		154445647	manufacture(70445-267)