LIP BALM COFFEE 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 Coffee Flavored

Purpose

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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, Coffee 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

COFFEE FLAVORED SPF 15 NATURAL BEESWAX LIP BALM

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DRUG FACTS			Net Wt. : 0.15 oz / 4.2 g
Active Ingredien Octinoxate Octyl Salicylate Oxybenzone Uses Helps preve	te 3.6% Sunscree icylate 2.5%		Inactive Ingredients: Hydrogenated Soybean Oil, Sunflower Oil, White Bees Wax Pastilles, Cocoa Butter, Shea Butter, Vitamin E, Aloe Vera Gel, Coffee Flavoring.
Warnings			time in the sun increases your
only to help preve	ent sunbur		This product has been shown cancer or early skin aging.
 For external use of Do not use on date 		broken skin.	
 Stop use and ask 	-		
			es. Rinse with water to remove.
Keep out of reach a Poison Control (wed, get medical help or contact
	concer mg.	nt away.	
Directions		10.000	
• Apply liberally 1	5 minute	es before su	in exposure
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Directions • Apply liberally 1 • Use a water resi	5 minute istant sur every 2	es before su nscreen if s hours	in exposure wimming or sweating
Directions • Apply liberally 1 • Use a water resi • Reapply at least • Children under (5 minute istant sur every 2 6 months	es before su nscreen if s hours s: Ask a doo	in exposure wimming or sweating

LIP BALM COFFEE FLAVORED

spf 15 lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70445-255
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: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	1.5 g in 1 g			

Inactive Ingredients	
Ingredient Name	Strength
HYDRO GENATED SO YBEAN OIL (UNII: A2M91M918C)	
COCOA BUTTER (UNII: 512OYT1CRR)	
SHEA BUTTER (UNII: K49155WL9Y)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)	
WHITE WAX (UNII: 7G1J5DA97F)	

SUNFLOWER OIL (UNII: 3W1JG795YI)						
Product Character	ristics					
Color		white	Score			
Shape			Size			
Flavor		COFFEE	Imprint (Code		
Contains						
Packaging						
# Item Code		Package Description		Marketing Start Date	Marketing E	End Date
1 NDC:70445-255-01	5 g in 1 TUBE; Type 0: Not a Combination Product		roduct	09/11/2009		
Marketing Information						
Marketing Category	Applica	tion Number or Monograph	Citation	Marketing Start Date	Marketing I	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(70445-255)

Revised: 3/2017

Webb Business Promotions