

## **LIP BALM CHOCOLATE PEPPERMINT 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 Chocolate Peppermint 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, Chocolate and Peppermint 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

**CHOCOLATE PEPPERMINT FLAVORED SPF 15 NATURAL BEESWAX LIP BALM**

**CHOCOLATE PEPPERMINT FLAVORED  
SPF 15 NATURAL BEESWAX LIP BALM**

<b>DRUG FACTS</b>		<b>Net Wt. : 0.15 oz / 4.2 g</b>
<b>Active Ingredients</b>	<b>Purpose</b>	<b>Inactive Ingredients:</b> Hydrogenated Soybean Oil, Sunflower Oil, White Bees Wax Pastilles, Cocoa Butter, Shea Butter, Vitamin E, Aloe Vera Gel, Chocolate Peppermint Flavoring.
Octinoxate 3.6%	Sunscreen	
Octyl Salicylate 2.5%		
Oxybenzone 1.5%		
<b>Uses</b>	Helps prevent sunburn	
<b>Warnings</b>		
<ul style="list-style-type: none"> <li>• <b>Skin Cancer/Skin Aging Alert:</b> 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, <b>not</b> skin cancer or early skin aging.</li> <li>• <b>For external use only.</b></li> <li>• <b>Do not use</b> on damaged or broken skin.</li> <li>• <b>Stop use and ask a doctor</b> if rash occurs.</li> <li>• <b>When using this product</b> keep out of eyes. Rinse with water to remove.</li> <li>• <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>		
<b>Directions</b>		
<ul style="list-style-type: none"> <li>• Apply liberally 15 minutes before sun exposure</li> <li>• Use a water resistant sunscreen if swimming or sweating</li> <li>• Reapply at least every 2 hours</li> <li>• Children under 6 months: Ask a doctor</li> </ul>		
<b>Other Information:</b> Protect this product from excessive heat and direct sun		

**LIP BALM CHOCOLATE PEPPERMINT FLAVORED**

spf 15 lipstick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70445-259
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.6 g in 1 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.5 g in 1 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1.5 g in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>HYDROGENATED SOYBEAN OIL</b> (UNII: A2M91M918C)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	

WHITE WAX (UNII: 7G1J5DA97F)

SUNFLOWER OIL (UNII: 3W1JG795YI)

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	CHOCOLATE, PEPPERMINT	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70445-259-01	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(70445-259)

Revised: 3/2017

Webb Business Promotions