

## **LIP BALM COCONUT 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 Coconut 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, Coconut 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

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

**COCONUT 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, Coconut 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  |                |   |
| <b>Dist. by:</b> Webb Eagan, MN 55121  |                | <b>Made in USA.</b>   |

**LIP BALM COCONUT FLAVORED**

spf 15 lipstick

**Product Information**

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70 445-256 |
| <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: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) | 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)       |          |
| <b>WHITE WAX</b> (UNII: 7G1J5DA97F)                |          |

SUNFLOWER OIL (UNII: 3W1JG795YI)

### Product Characteristics

|                 |         |                     |  |
|-----------------|---------|---------------------|--|
| <b>Color</b>    | white   | <b>Score</b>        |  |
| <b>Shape</b>    |         | <b>Size</b>         |  |
| <b>Flavor</b>   | COCONUT | <b>Imprint Code</b> |  |
| <b>Contains</b> |         |                     |  |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70445-256-01 | 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(70445-256) |

Revised: 3/2017

Webb Business Promotions