#### LIP BALM ORANGE CRUSH 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 Orange Crush 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, Orange Crush 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

## ORANGE CRUSH FLAVORED SPF 15 NATURAL BEESWAX LIP BALM

#### ORANGE CRUSH FLAVORED SPF 15 NATURAL BEESWAX LIP BALM

| DRUG FACTS   |  | Net Wt. : 0.15 oz / 4.2 g                             |   |  |  |
|--|--|---|---|--|--|
| Active IngredientsOctinoxate3.6%Octyl Salicylate2.5%Oxybenzone1.5%                               |  | Sunscreen   | Inactive Ingredients: Hydrogenated<br>Soybean Oil, Sunflower Oil, White<br>Bees Wax Pastilles, Cocoa Butter,<br>Shea Butter, Vitamin E, Aloe Vera |  |  |
| Uses Helps prev  | ent sunbu  | rn  | Gel, Orange Crush Flavoring.  |  |  |
| Warnings   |  |   |   |  |  |
|  |  |   | time in the sun increases your  |  |  |
|  |  |   | This product has been shown   |  |  |
| only to help preve   | ent sunbui                                       | rn, <b>not</b> skin o                                 | ancer or early skin aging.  |  |  |
| <ul> <li>For external use of</li> </ul>  | only.  |   |   |  |  |
| <ul> <li>Do not use on dat</li> </ul>  | maged or   | broken skin.  |   |  |  |
| <ul> <li>Stop use and ask</li> </ul>   | a doctor i                                       | f rash occurs   |   |  |  |
| •  |  |   | es. Rinse with water to remove.   |  |  |
|  |  |   | wed, get medical help or contact  |  |  |
|  | · ······   | ent in strano.  |   |  |  |
| a Poison Control (   | Center righ                                      | nt away.  |   |  |  |
| a Poison Control (   | Center rig                                       | nt away.  |   |  |  |
| Directions   |  |   |   |  |  |
| • Apply liberally 1  | .5 minute  | es before su  | in exposure   |  |  |
| <ul> <li>Directions</li> <li>Apply liberally 1</li> </ul>  | .5 minute  | es before su  |   |  |  |
| <ul> <li>Directions</li> <li>Apply liberally 1</li> </ul>  | .5 minute<br>istant sur                          | es before su<br>nscreen if s                          | in exposure   |  |  |
| Directions<br>• Apply liberally 1<br>• Use a water res   | .5 minute<br>istant sur<br>: every 2             | es before su<br>nscreen if s<br>hours                 | in exposure<br>wimming or sweating  |  |  |
| Directions<br>• Apply liberally 1<br>• Use a water res<br>• Reapply at least<br>• Children under | .5 minute<br>istant sur<br>: every 2<br>6 months | es before su<br>nscreen if s<br>hours<br>s: Ask a doo | in exposure<br>wimming or sweating  |  |  |

## LIP BALM ORANGE CRUSH FLAVORED

spf 15 lipstick

| Product Information     |                |                    |               |  |  |
|-------------------------|----------------|--------------------|---------------|--|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:70445-242 |  |  |
| 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: 5120 YT1CRR)              |          |  |  |  |
| SHEA BUTTER (UNII: K49155WL9Y)                |          |  |  |  |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)          |          |  |  |  |
| .ALPHATOCOPHEROL (UNII: H4N855PNZ1)           |          |  |  |  |

| WHITE WAX (UNII: 7G1J5DA97F) |   |              |  |        |                      |                    |         |
|------------------------------|---|--------------|--|--------|----------------------|--------------------|---------|
| st                           | SUNFLOWER OIL (UNII: 3W1JG795YI)  |              |  |        |                      |                    |         |
|                              |   |              |  |        |                      |                    |         |
| _                            |   |              |  |        |                      |                    |         |
| P                            | roduct Characte   | ristics      |  |        |                      |                    |         |
| С                            | olor  |              | white  | Score  |                      |                    |         |
| SI                           | ape   |              |  | Size   |                      |                    |         |
| Fl                           | avor  |              | ORANGE   | Imprin | t Code               |                    |         |
| С                            | ontains   |              |  |        |                      |                    |         |
|                              |   |              |  |        |                      |                    |         |
| _                            |   |              |  |        |                      |                    |         |
| P                            | ackaging  |              |  |        |                      |                    |         |
| #                            | Item Code   |              | Package Description                              |        | Marketing Start Date | Marketing End Date |         |
| 1                            | NDC:70445-242-01  | 5 g in 1 TUE | 5 g in 1 TUBE; Type 0: Not a Combination Product |        | 09/11/2009           |                    |         |
|                              |   |              |  |        |                      |                    |         |
|                              |   |              |  |        |                      |                    |         |
| Marketing Information        |   |              |  |        |                      |                    |         |
| N                            | Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date |              |  |        |                      |                    | nd Date |
| 0                            | ГС 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(70445-242) |  |  |  |

Revised: 3/2017

Webb Business Promotions