

**BROAD SPECTRUM SPF 15 CITRUS LIP BALM- broad spectrum spf 15 citrus lip balm stick**  
**Raining Rose, Inc**

*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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**Active Ingredients**

Avobenzone 2.0%

Octinoxate 6.5%

Octisalate 5.0%

Octocrylene 1.5%

**Purpose**

Sunscreen

**Warnings**

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 well with water to remove.

**Keep out of reach of children**

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

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 of age: **Ask a doctor**

**Inactive ingredients:**

Petrolatum, Mineral Oil, Paraffin Wax, Flavor, Ozokerite Wax, Coconut Oil, Tocopherol, Soybean Oil.

# Package Label

11/11/11 11:11 AM

## Broad Spectrum SPF 15 Sunscreen Citrus Lip Balm

### Drug Facts

#### Active Ingredients:

Avobenzone	2.0%
Octinoxate	6.5%
Octisalate	5.0%
Octocrylene	1.5%

### Drug Facts (continued)

Uses • Helps prevent sunburn

#### Warnings

• For external use only • Do not use on damaged skin • Stop use and ask a doctor if you have a rash or irritation while using this product • keep out of eyes. Rinse with water if contact occurs. Keep out of reach of children. If swallowed, or contact a Poison Control Center right away.

Directions • apply liberally 15 minutes before sun exposure • use as a water resistant sunscreen if swimming or sweating • Reapply every 2 hours • Children under 6 months of age: Ask a doctor before use. Sun Protection Measures Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease your risk, use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: • limit time in the sun • wear long sleeved shirts, pants, hats, and sunglasses

Inactive Ingredients: Petroleum, Mineral Oil, Citrus Flavor, Ozokerite Wax, Coconut Oil, Tocopherol, Soybean Lecithin

#### Other Information

Protect this product from excessive heat and direct sun.

Dist. by: Company name, city, state, zip

2011  
11/11/11  
11:11 AM

broad spectrum spf 15 citrus lip balm stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65692-0548
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.21 g in 4.25 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.09 g in 4.25 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.06 g in 4.25 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.28 g in 4.25 g

### Inactive Ingredients

Ingredient Name	Strength
COCONUT OIL (UNII: Q9L0O73W7L)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
CERESIN (UNII: Q1LS2UJO3A)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CITRUS	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0548-1	4.25 g in 1 TUBE; Type 0: Not a Combination Product	02/17/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/17/2020	

**Labeler** - Raining Rose, Inc (083819404)