

**SUN SHADES LIP BALM BUTTER RUM- avobenzone 2.5%, octinoxate 6%, oxybenzone 3% stick**

**Melaleuca 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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**Sun Shades Lip Balm - Sunscreen**

**Butter Rum - Broad-spectrum SPF 15**

**Active ingredients**

Avobenzone 2.5%, Octinoxate 6%, Oxybenzone 3%

**Purpose**

Sunscreen

**Uses**

■ helps prevent sunburn ■ if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

**Warnings**

**For external use only**

**Do not use** on damaged or broken skin

**When using this product** keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor** if rash occurs

**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

■ reapply at least every 2 hours ■ use a water-resistant sunscreen if swimming or sweating ■ children under 6 months of age: ask a doctor

■ **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad-spectrum SPF value of 15 or higher and other sun protection measures including: ■ limit time in the sun, especially from 10 a.m.-2 p.m. ■ wear long-sleeve shirts, pants, hats, and sunglasses

**Other information**

■ dermatologist and allergy tested

■ protect this product from excessive heat and direct sun ■ do not store at temperatures below 32°F (0°C) or above 120°F (49°C)

## Inactive Ingredients

ammonium glycyrrhizate, beeswax, C12-15 alkyl benzoate, cetyl esters, ethylene/VA copolymer, euphorbia cerifera (candillia) wax, flavor petrolatum USP, simmondsia chinensis (jojoba) seed oil, stearyl dimethicone, theobroma cacao (cocoa) seed butter, tocopheryl acetate (vitamin E USP)

**Melaleuca**  
**SUN SHADES™**  
 Lip Balm-Sunscreen  
*Butter Rum*  
 BROAD-SPECTRUM SPF 15  
 Jojoba, Cocoa Butter, Beeswax, Vitamin E  
 NET WT 0.15 OZ (4.25 g)

Melaleuca, Inc. • Idaho Falls, ID 83402-6003 • To order: 1-800-282-3000  
 www.melaleuca.com • Product of USA #7106 08/12U  
 NOT FOR RESALE IN CANADA

**Drug Facts**

Active ingredients	Purpose
Avobenzone 2.5%, Octinoxate 6%, Oxybenzone 3%	Sunscreen

**Uses**  
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**Drug Facts (continued)**

**Warnings**  
 For external use only  
 Do not use on damaged or broken skin  
 When using this product keep out of eyes. Rinse with water to remove.  
 Stop use and ask a doctor if rash occurs  
 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  
 ■ reapply at least every 2 hours ■ use a water-resistant sunscreen if swimming or sweating  
 ■ children under 8 months of age: ask a doctor  
 ■ Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and

**Drug Facts (continued)**  
 early skin aging. To decrease this risk, regularly use a sunscreen with a broad-spectrum SPF value of 15 or higher and other sun protection measures including: ■ limit time in the sun, especially from 10 a.m.–2 p.m. ■ wear long-sleeve shirts, pants, hats, and sunglasses

**Other Information**  
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## SUN SHADES LIP BALM BUTTER RUM

avobenzone 2.5%, octinoxate 6%, oxybenzone 3% stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54473-214
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.1175 g in 4.25 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.282 g in 4.25 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.141 g in 4.25 g

**Inactive Ingredients**

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
CERESIN (UNII: Q1LS2UJO3A)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ETHYLENE-VINYL ACETATE COPOLYMER (40% VINYL ACETATE) (UNII: L5F16ZG4ZU)	
JOJOBA OIL (UNII: 724GKU717M)	
PETROLATUM (UNII: 4T6H12BN9U)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CANDELILLA WAX (UNII: WL0328HX19)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-214-01	4.25 g in 1 APPLICATOR; Type 0: Not a Combination Product	10/01/2015	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/01/2012	

**Labeler** - Melaleuca Inc. (139760102)**Registrant** - Melaleuca Inc. (139760102)**Establishment**

Name	Address	ID/FEI	Business Operations
Melaleuca Inc.		079711683	manufacture(54473-214)