

**SUN SHADES LIP BALM COCONUT SMOOTHIE- avobenzene, octinoxate, oxybenzone 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.

Sun Shades Lip Balm - Sunscreen

Pink Grapefruit - Broad-spectrum SPF 15

Active ingredients

Avobenzene 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

Other Information

■ 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

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

avobenzone, octinoxate, oxybenzone stick

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54473-259 |
| Route of Administration | 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: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | 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:54473-259-01 | 4.25 g in 1 APPLICATOR; Type 0: Not a Combination Product | 02/01/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 05/14/2015 | |

Labeler - Melaleuca Inc. (139760102)

Registrant - Melaleuca Inc. (139760102)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------|---------|-----------|------------------------|
| Melaleuca Inc. | | 079711683 | manufacture(54473-259) |

Revised: 5/2017

Melaleuca Inc.