

SUN SHADES LIP BALM KEY LIME PIE- 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.

**Sun Shades Lip Balm - Sunscreen
Key Lime Pie - Broad-spectrum SPF 15**

Active ingredients

Avobenzone 2.5%, Octinoxate 6%, Oxybenzone 3%

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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)



<p>Drug Facts (continued)</p> <p>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</p> <p>Other information</p> <p>■ 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)</p> <p>Inactive ingredients</p> <p>petrolatum USP, beeswax, simmondsia chinensis (jojoba) seed oil, euphorbia cerifera, (candelilla) 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</p>
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avobenzone 2.5%, octinoxate 6%, oxybenzone 3% stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-257
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: 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:54473-257-01	4.25 g in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/30/2014	

Labeler - Melaleuca Inc. (139760102)

Registrant - Melaleuca Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
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Melaleuca Inc.		079287544	manufacture(54473-257)
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Revised: 3/2013

Melaleuca Inc.