

SUN SHADES LIP BALM POMEGRANATE SPF 15- octinoxate and 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.

Drug Facts

Active Ingredients: Octinoxate 7.5% w/w, Oxybenzone 3% w/w.

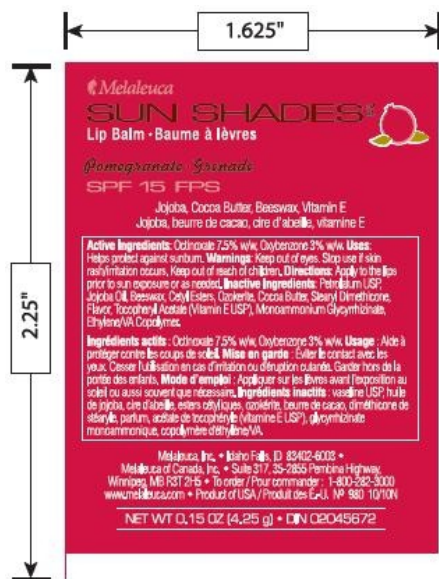
Uses: Helps protect against sunburn.

Warnings: Keep out of eyes. Stop use if skin rash/irritation occurs. Keep out of reach of children.

Directions: Apply to the lips prior to sun exposure or as needed.

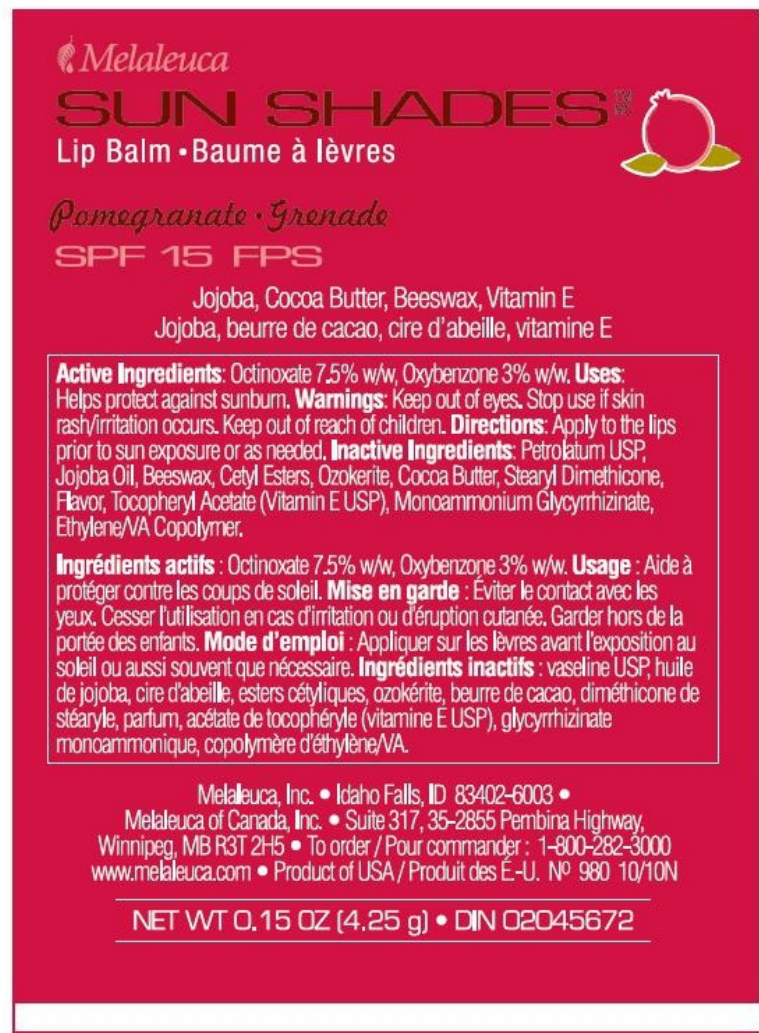
Inactive Ingredients: Petrolatum USP, Jojoba Oil, Beeswax, Cetyl Esters, Ozokerite, Cocoa Butter, Stearyl Dimethicone, Flavor, Tocopheryl Acetate (Vitamin E USP), Monoammonium Glycyrhizinate, Ethylene/VA Copolymer.

image of label



Glue Area

Scaled 200%



SUN SHADES LIP BALM POMEGRANATE SPF 15
octinoxate and oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-168
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	75 mg in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Petrolatum (UNII: 4T6H12BN9U)	
Jojoba Oil (UNII: 724GKU717M)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Cetyl Esters Wax (UNII: D072FFP9GU)	
Ceresin (UNII: Q1LS2UJO3A)	
Cocoa Butter (UNII: 512OYT1CRR)	
Vitamin E Acetate (UNII: 9E8X80D2L0)	
Glycyrrhizin, Ammoniated (UNII: 3VRD35U26C)	
ETHYLENE-VINYL ACETATE COPOLYMER (40% VINYL ACETATE) (UNII: L5F16ZG4ZU)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	POMEGRANATE (Pomegranate)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-168-01	4.2 g in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2010	

Labeler - Melaleuca, Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
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