

SUN SHADES 15 LIP BALM CRANBERRY TANGERINE- 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.

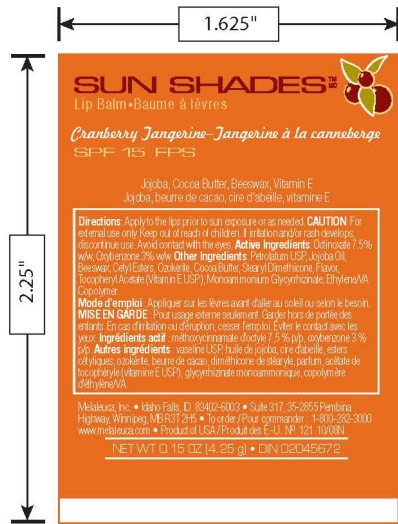
SUN SHADES Cranberry Tangerine Label Information

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

Caution: For external use only. Keep out of reach of children. If irritation develops, discontinue use. Avoid contact with the eyes.

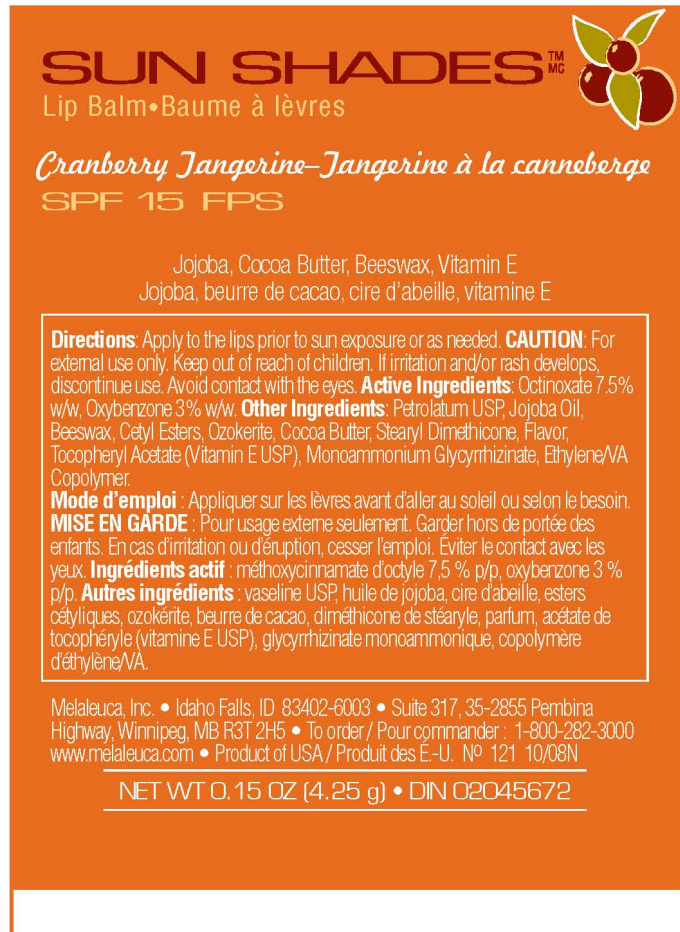
Active Ingredients: Octinoxate 7.5% w/w. Oxybenzone 3.0% w/w.

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



Glue Area

Scaled 200%



Glue Area

SUN SHADES 15 LIP BALM CRANBERRY TANGERINE

octinoxate and oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-160	
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
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)				
ETHYLENE-VINYL ACETATE COPOLYMER (40% VINYL ACETATE) (UNII: L5F16ZG4ZU)				
Glycyrrhizin, Ammoniated (UNII: 3VRD35U26C)				
Petrolatum (UNII: 4T6HI2BN9U)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-160-01	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	10/01/2008		

Labeler - Melaleuca, Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		139760102	manufacture

Revised: 12/2010

Melaleuca, Inc.