

**SUN SHADES 15 LIP BALM LEMON GUM DROP- 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.*

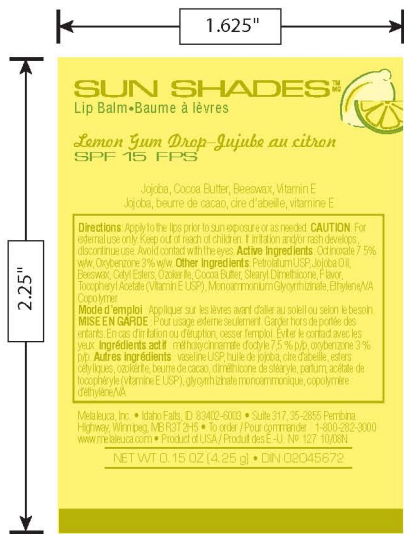
**SUN SHADES Lemon Gum Drop Label Information**

**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.

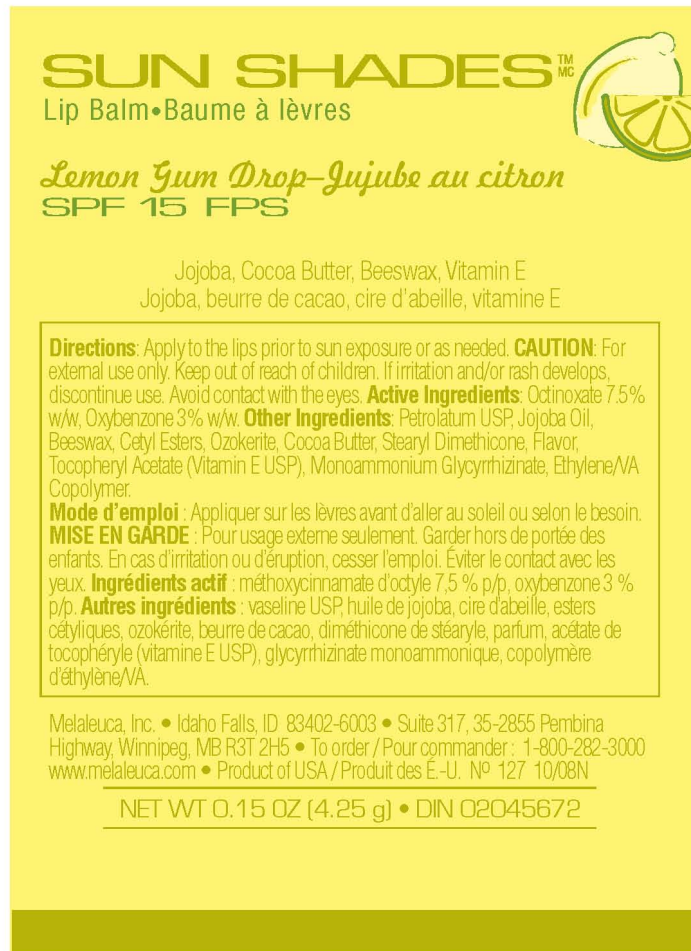
**Active Ingredients:** Octinoxate 7.5% w/w. Oxybenzone 3.0% w/w.

**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 LEMON GUM DROP**  
 octinoxate and oxybenzone stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54473-162	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)		Octinoxate	75 mg in 1 g	
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)		Oxybenzone	30 mg in 1 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>				<b>Strength</b>
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)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:54473-162-01	4.2 g in 1 APPLICATOR		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part352	10/01/2007		

**Labeler** - Melaleuca, Inc. (139760102)

### Establishment

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

Revised: 12/2010

Melaleuca, Inc.