

**LBEL LIP MOISTURIZER SPF 18- octinoxate, oxybenzone, and titanium dioxide lipstick
Ventura Corporation LTD**

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.

**L'BEL
LIP MOISTURIZER SPF 18**

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Octinoxate 7.0%	Sunscreen
Oxybenzone 3.0%	Sunscreen
Titanium Dioxide 0.8%	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.
- **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 and evenly 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

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive ingredients

Octyldodecanol, caprylic/capric triglyceride, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), copernicia cerifera cera (copernicia cerifera (carnauba) wax), butyrospermum parkii butter (butyrospermum parkii (shea) butter), hydrogenated polyisobutene, silica, propylparaben, cera

microcristallina (microcrystalline wax), aqua (water), tocopheryl acetate, petrolatum, phospholipids, bht, parfum (fragrance), cholesterol, crambe maritima extract, cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, maltodextrin, zea mays starch (zea mays(corn) starch), phenoxyethanol, sodium hyaluronate, methylparaben, butylparaben, ethylparaben, isobutylparaben.

PR: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926.

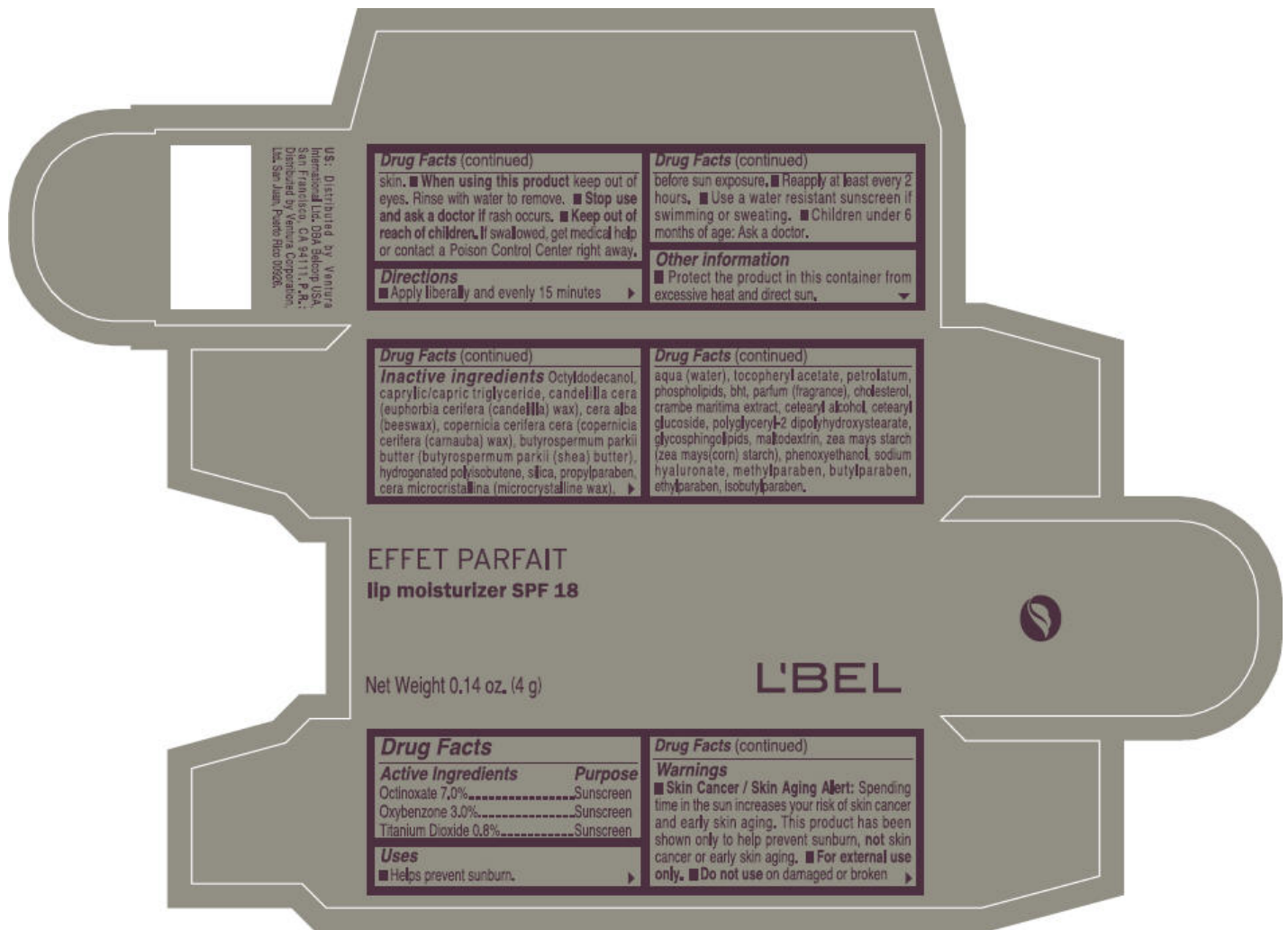
PRINCIPAL DISPLAY PANEL - 4 g Tube Box

EFFET PARFAIT

lip moisturizer SPF 18

Net Weight 0.14 oz. (4 g)

L'BEL



LBEL LIP MOISTURIZER SPF 18

octinoxate, oxybenzone, and titanium dioxide lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-226
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.03 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.08 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SHEA BUTTER (UNII: K49155WL9Y)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STARCH, CORN (UNII: O8232NY3SJ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BUTYLPARABEN (UNII: 3QP1I03FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-226-02	1 in 1 BOX		
1	NDC:13537-226-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/16/2013	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-226)

Revised: 12/2013

Ventura Corporation LTD