

**LBEL LIP MOISTURIZER SPF 18- octinoxate, oxybenzone, and titanium dioxide lipstick**  
**Ventura International 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.*

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**L'BEL**  
**Lip Moisturizer SPF 18**

**Drug Facts**

<b>Active Ingredients</b>	<b>Purpose</b>
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.

**US:** Distributed by Ventura International Ltd. DBA Belcorp USA, San Francisco, CA 94111

**PRINCIPAL DISPLAY PANEL - 4 g Tube Carton**

EFFET PARFAIT

**lip moisturizer SPF 18**

Net Weight 0.14 oz. (4 g)

**L'BEL**

**Drug Facts** (continued)

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**Directions**

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**Drug Facts** (continued)

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**Other information**

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

**Drug Facts** (continued)

**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), ▶

**Drug Facts** (continued)

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.

# EFFET PARFAIT

## lip moisturizer SPF 18

Net Weight 0.14 oz. (4 g)

# L'BEL

**Drug Facts**

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

**Uses**

■ Helps prevent sunburn. ▶

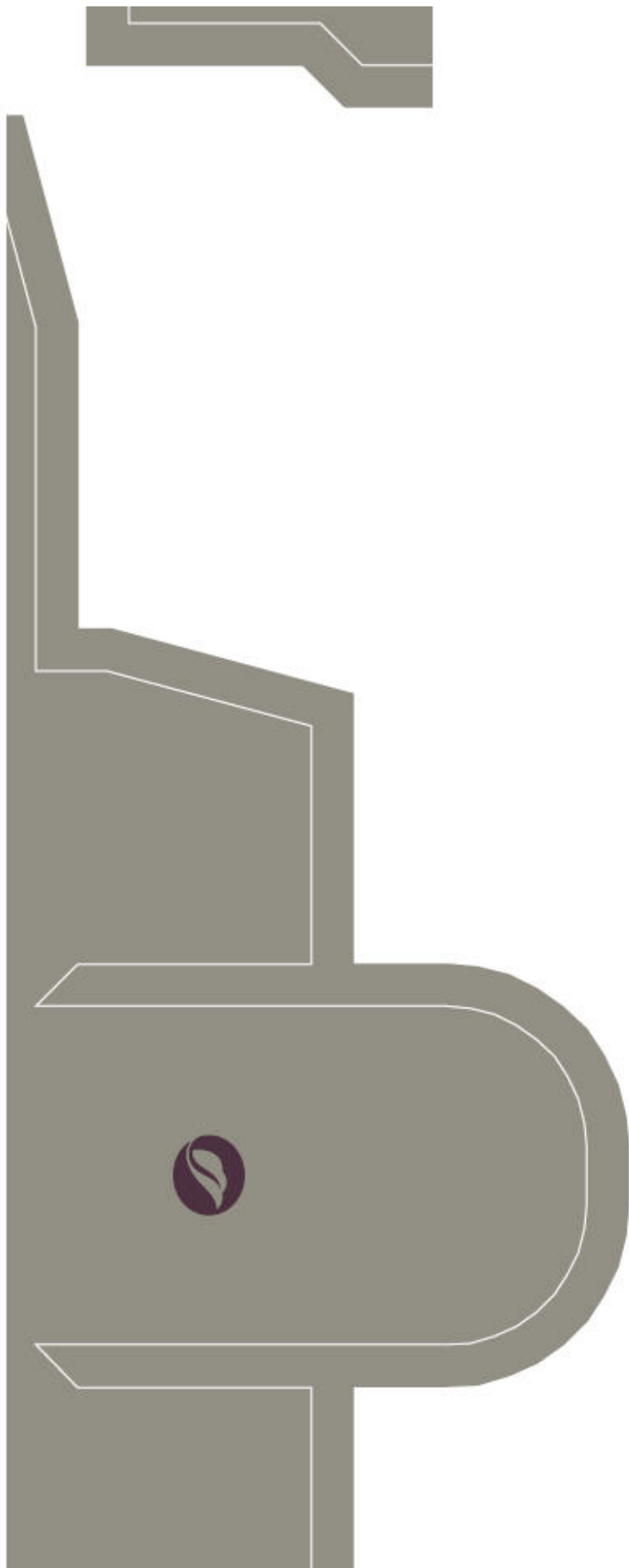
**Drug Facts** (continued)

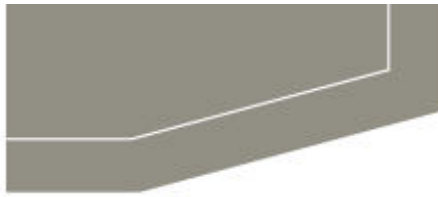
**Warnings**

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## LBEL LIP MOISTURIZER SPF 18

octinoxate, oxybenzone, and titanium dioxide lipstick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14783-226
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>Octyldodecanol</b> (UNII: 461N1O614Y)	
<b>medium-chain triglycerides</b> (UNII: C9H2L21V7U)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>.alpha.-tocopherol acetate</b> (UNII: 9E8X80D2L0)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>polyglyceryl-2 dipolyhydroxystearate</b> (UNII: 9229XJ4V12)	
<b>maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>butylparaben</b> (UNII: 3QPII1U3FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-226-02	1 in 1 BOX		
1	NDC:14783-226-01	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 International LTD (603192787)**Establishment**

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-226)

Revised: 12/2013

Ventura International LTD