

**LBEL EFFET PARFAIT LIP MOISTURIZER SPF 18 FM HIDRATANTE PARA LABIOS FPS 18 FM- 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 EFFET PARFAIT Lip moisturizer SPF 18 FM**

***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
OCTINOXATE 7.00 %	Sunscreen
OXYBENZONE 3.00 %	Sunscreen
TITANIUM DIOXIDE 0.80 %	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 damage 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.
- Children under 6 months of age: Ask a doctor.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Apply lipstick following the curves of natural lip line. For added definition, use with a lip pencil.

**Other information**

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

**Inactive ingredients**

OCTYLDODECANOL, CAPRYLIC/CAPRIC TRIGLYCERIDE, EUPHORBIA CERIFERA (CANDELILLA) WAX, SYNTHETIC BEESWAX, BUTYROSPERMUM PARKII (SHEA) BUTTER, COPERNICIA CERIFERA (CARNAUBA) WAX, HYDROGENATED POLYISOBUTENE, SILICA,

MICROCRYSTALLINE WAX, PHENOXYETHANOL, TOCOPHERYL ACETATE,  
PETROLATUM, PHOSPHOLIPIDS, CAPRYLYL GLYCOL, FRAGRANCE, PENTAERYTHRITYL  
TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE, CHLORPHENESIN, CHOLESTEROL,  
CRAMBE MARITIMA EXTRACT, BEESWAX, CETEARYL ALCOHOL, CETEARYL  
GLUCOSIDE, POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE, GLYCOSPHINGOLIPIDS.

Dist. by Ventura Int Ltd. DBA  
Belcorp USA, Miami, FL 33126.

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

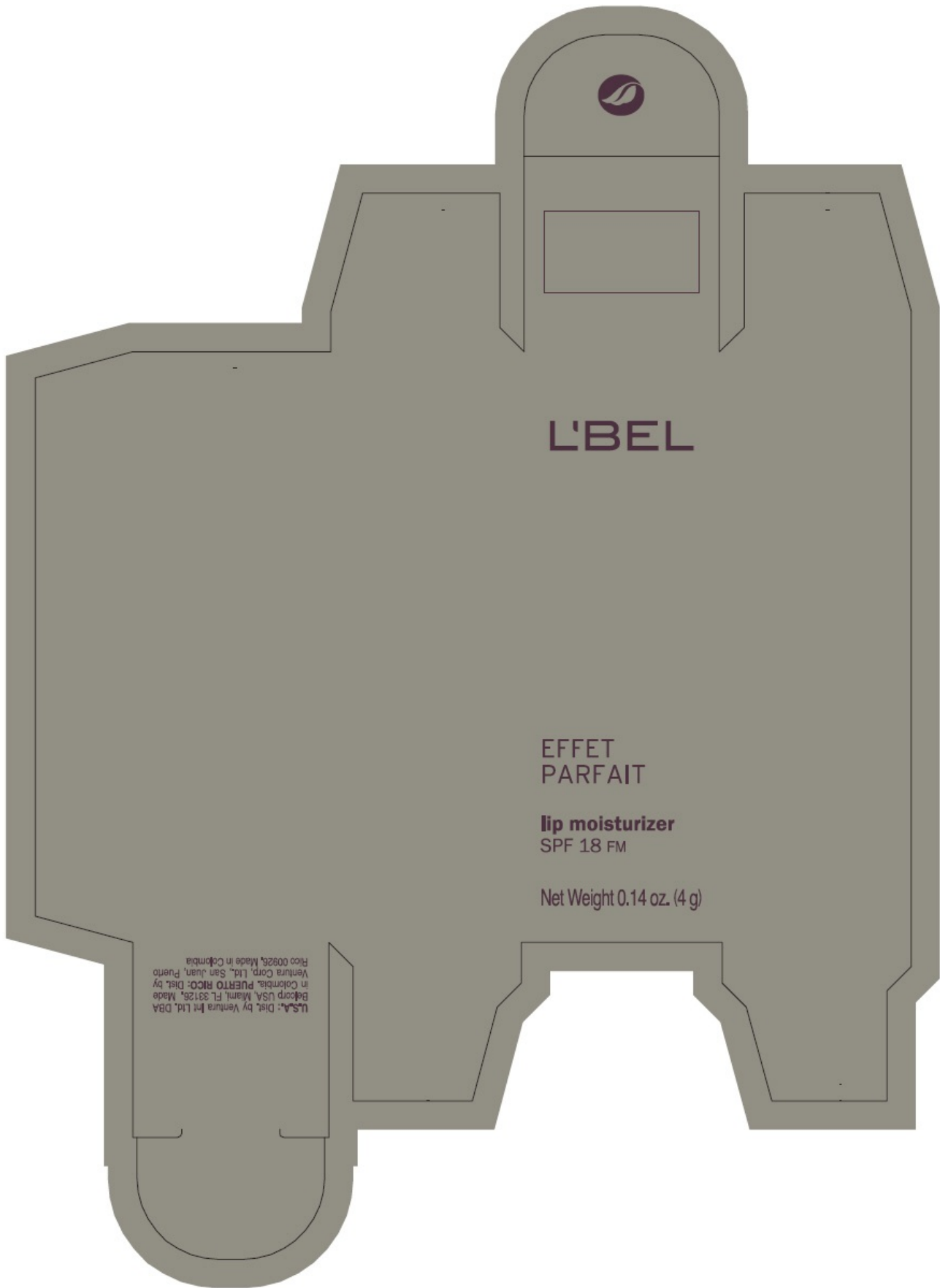
**L'BEL**

EFFET  
PARFAIT

**lip moisturizer**

SPF 18 FM

Net Weight 0.14 oz. (4 g)



10

1

<b>Inactive ingredients</b> (continued)	
CHOLESTEROL, CRAMBE MARITIMA EXTRACT, BEESWAX,	
CETEARYL ALCOHOL, CETEARYL GLUCOSIDE,	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE,	

<b>Drug Facts</b>	
<b>Active Ingredients</b> .....	<b>Purpose</b>
OCTINOXATE 7,00%	Sunscreen
OXYBENZONE 3,00%	Sunscreen

GLYCOSPHINGOLIPIDS. TITANIUM DIOXIDE 0.80% Sunscreen

2

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4

**Drugs Facts** (continued)  
**Uses**  
 ■ Helps prevent sunburn.  
**Warnings**  
 ■ Skin Cancer / Skin Aging Alert: Spending time in the

**Drugs Facts** (continued)  
 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.

**Drugs Facts** (continued)  
 ■ 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.

5

6

**Drugs Facts** (continued)  
 ■ 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.

**Drugs Facts** (continued)  
 ■ Reapply at least every 2 hours.  
 ■ Use a water resistant sunscreen if swimming or sweating.  
 ■ Children under 6 months of age: Ask a doctor.  
 ■ Apply stick following the curves of natural lip line.

7

8

9

**Drugs Facts** (continued)  
 For added definition, use with a lip pencil.  
**Other information**  
 ■ Protect this product in this container from excessive heat and direct sun.

**Inactive ingredients** (continued)  
**Inactive ingredients** OCTYLDODECANOL, CAPRYLIC/CAPRIC TRIGLYCERIDE, EUPHORBIA CERIFERA (CANDELILLA) WAX, SYNTHETIC BEESWAX, BUTYROSPERMUM PARKII (SHEA) BUTTER, COPERNICIA CERIFERA

**Inactive ingredients** (continued)  
 (CARNAUBA) WAX, HYDROGENATED POLYISOBUTENE, SILICA, MICROCRYSTALLINE WAX, PHENOXYETHANOL, TOCOPHERYL ACETATE, PETROLATUM, PHOSPHOLIPIDS, CAPRYLYL GLYCOL, FRAGRANCE, PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE, CHLORPHENESIN.

## LBEL EFFET PARFAIT LIP MOISTURIZER SPF 18 FM HIDRATANTE PARA LABIOS FPS 18 FM

octinoxate, oxybenzone, and titanium dioxide lipstick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14783-865
<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	0.008 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>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)</b> (UNII: 255PIF62MS)
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)
<b>POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE</b> (UNII: 9229XJ4V12)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-865-02	1 in 1 BOX		
1	NDC:14783-865-01	4 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/08/2015	

**Labeler** - Ventura International LTD (603192787)

### Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-865)

Revised: 12/2015

Ventura International LTD