

**LBEL EFFET PARFAIT ROUGE VOLUMESSE- octinoxate and oxybenzone 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 ROUGE VOLUMESSE FPS 21**

**Active Ingredients**

Octinoxate (6.72 %), Oxybenzone (2.24 %).

**Purpose**

Sunscreen.

**Uses**

Helps prevent sunburn. Moderate sun protection product.

**Warnings**

Stop use if skin rash occurs.

**Directions**

Apply evenly before sun exposure and as needed. Apply lipstick following the curves of natural lip line. For added definition, use with a lip pencil.

**Other information**

Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin cancer, and other harmful effects of the sun.

**Inactive Ingredients**

Ricinus communis (castor) seed oil, caprylic/capric triglyceride, ethylhexyl palmitate, euphorbia cerifera (candelilla) wax, glyceryl isostearate, polyethylene, methyl hydrogenated rosin, lanolin oil, copernicia cerifera (carnauba) wax, isostearyl alcohol, polybutene, butyrospermum parkii (shea butter), ci 77019 (mica), beta-sitosterol, silica silylate, phenoxyethanol, menthol, octyldodecanol, dimethicone, triphenylmethane, luffa cylindrica seed oil, propylparaben, methylparaben, cera microcristallina (microcrystalline wax), sorbitan isostearate, parfum (fragrance), silica dimethyl silylate, petrolatum, phospholipids, butylparaben, ethylparaben, butylene glycol, cholesterol, isobutylparaben, trimethylsiloxysilicate, cera alba (beewax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, sodium hyaluronate, glycosphingolipids, palmitoyl oligopeptide. **May contain:** ci 77891 (titanium dioxide), ci 15850:1 (red 7 lake), ci 75470 (carmine), ci 77491, ci 77492, ci 77499 (iron oxides), ci 19140 (yellow 5 lake), ci 45380:2 (red 21 lake), ci 45410:1 (red 27 lake), ci 42090 (blue 1 lake), silica, bht, hydrogenated polyisobutene, palmitic acid, talc.

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

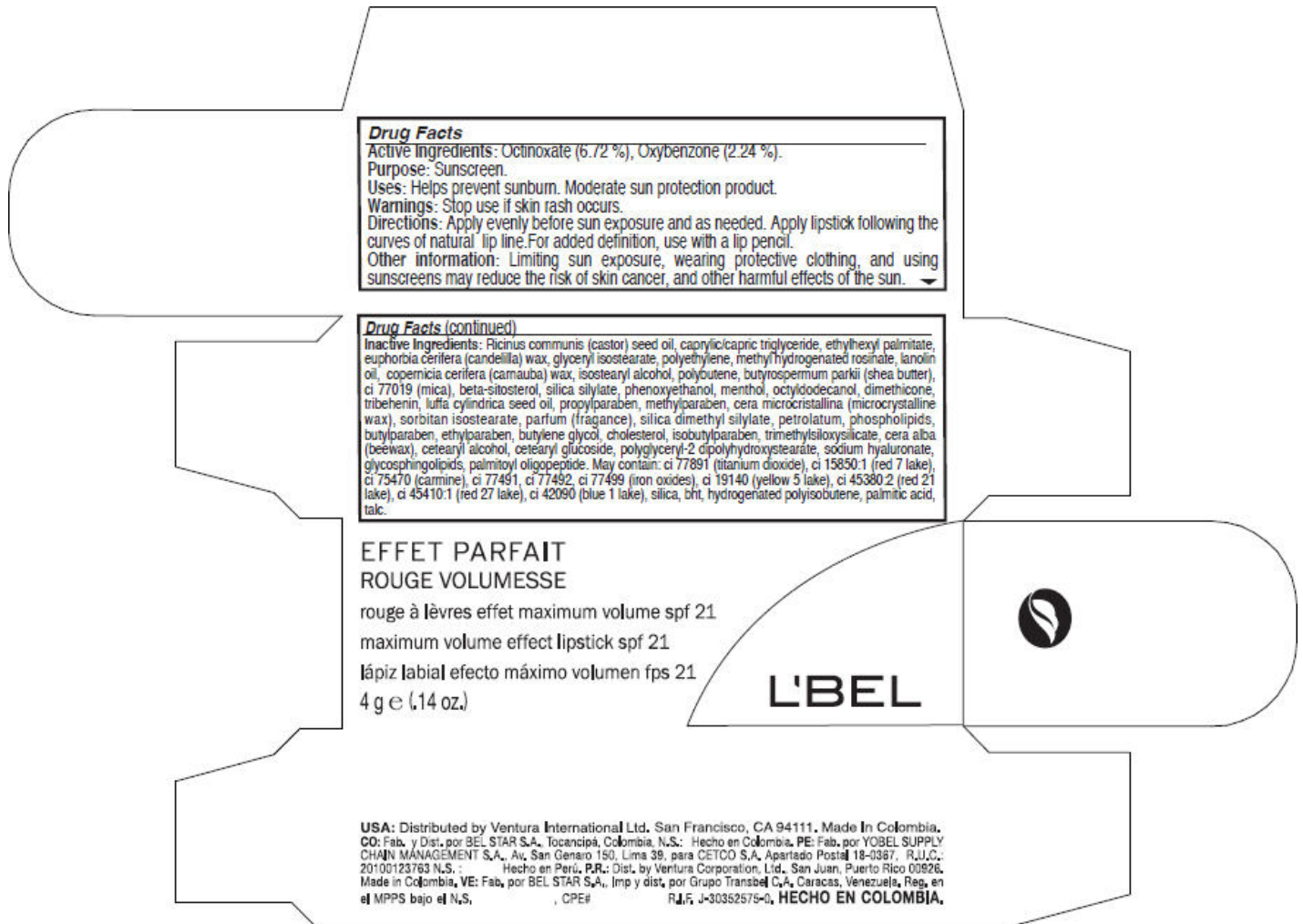
**PRINCIPAL DISPLAY PANEL - 4 g Carton**

EFFET PARFAIT  
ROUGE VOLUMESSE

maximum volume effect lipstick spf 21

4 g e (.14 oz.)

L'BEL



**LBEL EFFET PARFAIT ROUGE VOLUMESSE**

octinoxate and oxybenzone lipstick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-220
<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	0.2688 g in 4 g
<b>Oxybenzone</b> (UNII: 950OS7VE0Y) (Oxybenzone - UNII:950OS7VE0Y)	Oxybenzone	0.0896 g in 4 g

**Inactive Ingredients**

Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
ethylhexyl palmitate (UNII: 2865993309)	
candelilla wax (UNII: WL0328HX19)	
lanolin (UNII: 7EV65EAW6H)	
carnauba wax (UNII: R12CBM0EIZ)	
isostearyl alcohol (UNII: Q613OCQ44Y)	
shea butter (UNII: K49155WL9Y)	
mica (UNII: V8A1AW0880)	
.beta.-sitosterol (UNII: S347WMO6M4)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
phenoxyethanol (UNII: HIE492ZZ3T)	
menthol (UNII: L7T10EIP3A)	
octyldodecanol (UNII: 461N1O614Y)	
dimethicone (UNII: 92RU3N3Y1O)	
tribehenin (UNII: 8OC9U7TQZ0)	
luffa (UNII: F0R3Y60C6V)	
propylparaben (UNII: Z8IX2SC1OH)	
methylparaben (UNII: A218C7HI9T)	
sorbitan (UNII: 6O92ICV9RU)	
petrolatum (UNII: 4T6H12BN9U)	
butylparaben (UNII: 3QPIU3FV8)	
ethylparaben (UNII: 14255EXE39)	
butylene glycol (UNII: 3XUS85K0RA)	
cholesterol (UNII: 97C5T2UQ7J)	
isobutylparaben (UNII: 0QQJ25X58G)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
titanium dioxide (UNII: 15FIX9V2JP)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
aluminum oxide (UNII: LM26O6933)	
ferric oxide red (UNII: 1K09F3G675)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferrosoferric oxide (UNII: XM0M87F357)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
palmitic acid (UNII: 2V16EO95H1)	
talc (UNII: 7SEV7J4R1U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-220-62	1 in 1 BOX		

1	NDC:13537-220-61	4 g in 1 TUBE		
<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 FINAL	part352	08/15/2010		

**Labeler** - VENTURA INTERNATIONAL LTD., (602751344)

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VENTURA INTERNATIONAL LTD.,