

**LBEL COULEUR LUXE SUPREME LAQUE- octinoxate and oxybenzone lipstick**  
**Ventura International, Limited**

*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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**COULEUR LUXE SUPREME LAQUE**  
**liquid lipstick with long duration and shine SPF 16**

**Active Ingredients**

Octinoxate 7 % , Oxybenzone 3%

**Purpose**

sunscreen

**Uses**

Helps prevent sunburn

**Warnings**

Stop use if skin rash occurs

**Inactive ingredients**

octyldodecanol, glyceryl hydrogenated rosinat, polybutene, vp/eicosene copolymer, vp/hexadecene copolymer, cera alba (beeswax), isononyl isononanoate, isododecane, silica dimethyl silylate, ethylene/va copolymer, disteardimonium hectorite, propylene carbonate, phenoxyethanol, isostearyl alcohol, cera microcristallina (microcrystalline wax), petrolatum, bha, parfum (fragrance), phospholipids, methylparaben, cholesterol, butylparaben, ethylparaben, candelilla cera (euphorbia cerifera (candelilla) wax), copernicia cerifera cera (copernicia cerifera (carnauba ) wax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, isobutylparaben, propylparaben. **May contain:** Red 30 lake,,mica, red 7 lake, titanium dioxide, yellow 5 lake, ron oxides, red 21 lake, red 6 lake, talc, lauroyl lysine, carmine, orange 5, triethoxycaprylylsilane, C9-15 fluoroalcohol.

**USA:** Dist. by Ventura International Ltd. San Francisco, CA 94111. Made in Colombia. **PUERTO RICO:** Dist. by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

**PRINCIPAL DISPLAY PANEL - 7 ml Carton**

**COULEUR LUXE SUPREME LAQUE**

liquid **lipstick** with long duration and shine **SPF 16**

7 ml e (.23 fl.oz.)

**L'BEL**

(microcrystalline wax), petrolatum, bha, parfum (fragrance), phospholipids, methylparaben, cholesterol, butylparaben, ethylparaben, candelilla cera (euphorbia cerifera (candelilla) wax), copernicia cerifera cera (copernicia cerifera (carnauba) wax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, isobutylparaben, propylparaben. May contain: Red 30 lake, mica, red 7 lake, titanium dioxide, yellow 5 lake, iron oxides, red 21 lake, red 6 lake, talc, lauroyl lysine, carmine, triethoxycaprylsilane, C9-15 fluoroalcohol.

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**COULEUR LUXE SUPREME LAQUE**  
 liquid lipstick with long duration and shine SPF 16  
 labial líquido de gran duración y brillo FPS 16

7 ml e (.23 fl.oz.)

L'BEL

**Active Ingredients:** Octinoxate 7%, Oxybenzone 3%  
**Purpose:** Sunscreen.  
**Uses:** Helps prevent sunburn.  
**Warnings:** Stop use if skin rash occurs.  
**Inactive Ingredients:** Octyldodecanol, glyceryl hydrogenated rosinat, polybutene, vp/eicosene copolymer, vp/hexadecane copolymer, cera alba (beeswax), isononyl isononanoate, isododecane, silica dimethyl silylate, ethylene/va copolymer, disteardimonium hectorite, propylene carbonate, phenoxyethanol, isostearyl alcohol, cera microcristallina

## LBEL COULEUR LUXE SUPREME LAQUE

octinoxate and oxybenzone lipstick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14783-880
<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 mL in 1 mL
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.03 mL in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	

PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PETROLATUM (UNII: 4T6H12BN9U)
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)
METHYLPARABEN (UNII: A2I8C7HI9T)
CHOLESTEROL (UNII: 97C5T2UQ7J)
BUTYLPARABEN (UNII: 3QP1U3FV8)
ETHYLPARABEN (UNII: 14255EXE39)
CANDELILLA WAX (UNII: WL0328HX19)
CARNAUBA WAX (UNII: R12CBM0EIZ)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)
PROPYLPARABEN (UNII: Z8IX2SC10H)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
MICA (UNII: V8A1AW0880)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 6 (UNII: 481744AI4O)
TALC (UNII: 7SEV7J4R1U)
LAUROYL LYSINE (UNII: 113171Q70B)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-880-08	1 in 1 CARTON		
1	NDC:14783-880-07	7 mL in 1 TUBE, WITH APPLICATOR		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/05/2010	

**Labeler** - Ventura International, Limited (603192787)

### Establishment

Name	Address	ID/FEI	Business Operations
BelStar, S.A.		880160197	MANUFACTURE