

**LBEL COULEUR LUXE SUPREME LAQUE- octinoxate and oxybenzone 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.

**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 microcristalina

LBEL COULEUR LUXE SUPREME LAQUE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.07 mL in 1 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.03 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECANOL (UNII: 461N1O614Y)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
ISODODECANE (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: A2I8C7H9T)
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: Z8IX2SC1OH)
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:13537-020-02	1 in 1 CARTON		
1	NDC:13537-020-01	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	08/10/2011	

Labeler - Ventura Corporation Ltd. (602751344)

Establishment

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