

**LBEL COULEUR LUXE SUPREME XP- 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.

COULEUR LUXE SUPREME XP

Active Ingredients

Octinoxate (0.98 %), Oxybenzone (0.47 %), Titanium Dioxide (0.94 %).

Purpose

Sunscreen.

Uses

Helps prevent sunburn. Minimum 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 seed oil (ricinus communis (castor) seed oil), diisostearyl malate, caprylic/capric triglyceride, decyl oleate, ci 77019 (mica), ozokerite, cera alba (beeswax), copernicia cerifera (copernicia cerifera (carnauba)wax), candelilla cera (euphorbia cerifera (candelilla) wax), isopropyl lanolate, sorbitan sesquioleate, hydrogenated polyisobutene, vp/hexadecene copolymer, isostearyl neopentanoate, octyldodecano, parfum (fragrance), propylparaben, lecithin, bht, dimethicone, arachidyl propionate, tocopheryl acetate, retinyl palmitate, trimethylsiloxysilicate, ethyl linoleate, ethyl linolenate. May contain: ci 77891 (titanium dioxide), ci 77491, ci 77492, ci 77499 (iron oxides), ci 77163 (bismuth oxychloride), ci 15850 (red 6 lake), ci 19140 (yellow 5 lake), ci 15850 (red 7 lake), ci 45410 (red 27 lake), ci 45380 (red 21 lake), talc, ci 42090 (blue 1 lake), oleyl alcohol, c9-13 fluoroalcohol, phosphoric acid, ci 75470 (carmines).

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

PRINCIPAL DISPLAY PANEL - 4 g Carton

COULEUR LUXE SUPRÊME XP

lipstick with long duration and shine spf 8

4 g e (.14 oz.)

L'BEL



LBEL COULEUR LUXE SUPREME XP			
octinoxate, oxybenzone, and titanium dioxide lipstick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-083
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)		Octinoxate	0.0392 g in 4 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)		Oxybenzone	0.0188 g in 4 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)		Titanium Dioxide	0.0376 g in 4 g
Inactive Ingredients			

Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
decyl oleate (UNII: ZGR06DO97T)	
yellow wax (UNII: 2ZA36H0S2V)	
carnauba wax (UNII: R12CBM0EIZ)	
candelilla wax (UNII: WL0328HX19)	
sorbitan sesquioleate (UNII: 0W8RRI5W5A)	
propylparaben (UNII: Z8IX2SC1OH)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
dimethicone (UNII: 92RU3N3Y1O)	
arachidyl propionate (UNII: QV5DAH3MSB)	
vitamin a palmitate (UNII: 1D1K0N0VVC)	
ethyl linoleate (UNII: MJ2YTT4J8M)	
ferric oxide red (UNII: 1K09F3G675)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferrosoferric oxide (UNII: XM0M87F357)	
D&C red no. 6 (UNII: 481744AI4O)	
FD&C yellow no. 5 (UNII: I753WB2F1M)	
D&C red no. 28 (UNII: 767IP0Y5NH)	
talc (UNII: 7SEV7J4R1U)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
oleyl alcohol (UNII: 172F2WN8DV)	
phosphoric acid (UNII: E4GA8884NN)	
mica (UNII: V8A1AW0880)	
aluminum oxide (UNII: LM26O6933)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-083-62	1 in 1 BOX		
1	NDC:14783-083-61	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/15/2010	

Labeler - Ventura International LTD (603192787)