

**LBEL COULEUR LUXE ROUGE IRRESISTIBLE- 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.

**L'BEL
COULEUR LUXE ROUGE IRRÉSISTIBLE
maximum hydration lipstick SPF 17**

Active Ingredients

Octinoxate 7.1 % , Oxybenzone 1.6%

Purpose

sunscreen

Uses

Helps prevent sunburn

Warnings

Stop use if skin rash occurs

Inactive ingredients

ethylhexyl palmitate, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, polyethylene, polymethyl methacrylate, (butyrospermum parkii (shea butter), ozokerite, copernicia cerifera (carnauba) wax, tridecyl stearate, neopentyl glycol dicaprylate/dicaprate, octyldodecanol, disteardimonium hectorite, caprylic/capric triglyceride, phenoxyethanol, tocopheryl acetate, aloe barbadensis leaf extract, fragrance, microcrystalline wax, propylene carbonate, silica, methylparaben, petrolatum, phospholipids, bht, cholesterol, butylparaben, ethylparaben, crambe maritima extract, bha, euphorbia cerifera (candelilla) wax, beeswax, polyglyceryl-2 dipolyhydroxystearate, cetearyl glucoside, cetearyl alcohol, propylparaben, isobutylparaben, glycosphingolipids. **May contain:** mica, titanium dioxide, red 7 lake, iron oxides, yellow 5 lake, red 30 lake, red 21 lake, bismuth oxychloride, talc, red 40 lake, blue 1 lake, carmine, hydrogenated polyisobutene, palmitic acid.

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 - 4 g Carton

COULEUR LUXE ROUGE IRRÉSISTIBLE

maximum hydration **lipstick SPF 17**

4 g e (.14 oz.)

L'BEL

microcrystalline wax, propylene carbonate, silica, methylparaben, petrolatum, phospholipids, bht, cholesterol, butylparaben, ethylparaben, crambe maritima extract, bha, euphorbia cerifera (candelilla) wax, beeswax, polyglyceryl-2 dipolyhydroxystearate, cetearyl glucoside, cetearyl alcohol, propylparaben, isobutylparaben, glycosphingolipids. **May contain:** Mica, titanium dioxide, red 7 lake, iron oxides, yellow 5 lake, red 30 lake, red 21 lake, bismuth oxychloride, talc, red 40 lake, blue 1 lake, carmine, hydrogenated polyisobutene, palmitic acid.

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COULEUR LUXE ROUGE IRRÉSISTIBLE
maximum hydration lipstick SPF 17
lápiz labial máxima hidratación FPS 17

4 g e (14 oz.)

L'BEL

Active Ingredients: Octinoxate 7.1 %, Oxybenzone 1.6%.
Purpose: Sunscreen.
Uses: Helps prevent sunburn.
Warnings: Stop use if skin rash occurs.
Inactive Ingredients: Ethylhexyl palmitate, dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, polyethylene, polymethyl methacrylate, (butyrospermum parkii (shea butter), ozokerite, copernicia cerifera (carnauba) wax, tridecyl stearate, neopentyl glycol dicaprylate/dicaprate, octyldodecanol, disteardimonium hectorite, caprylic/capric triglyceride, phenoxyethanol, tocopheryl acetate, aloe barbadensis leaf extract, fragrance.

LBEL COULEUR LUXE ROUGE IRRESISTIBLE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-990
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.071 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.016 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SHEA BUTTER (UNII: K49155WL9Y)	
CERESIN (UNII: Q1LS2UJO3A)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	

OCTYLDODECANOL (UNII: 461N1O614Y)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HE492ZZ3T)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
METHYLPARABEN (UNII: A2I8C7HI9T)
PETROLATUM (UNII: 4T6H12BN9U)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CHOLESTEROL (UNII: 97C5T2UQ7J)
BUTYLPARABEN (UNII: 3QP1U3FV8)
ETHYLPARABEN (UNII: 14255EXE39)
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 21 (UNII: 08744Z6JNY)
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)
TALC (UNII: 7SEV7J4R1U)
FD&C RED NO. 40 (UNII: WZB9127XOA)
D&C BLUE NO. 4 (UNII: 0KSY80VYS3)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-990-05	12 in 1 CARTON		
1	NDC:14783-990-04	4 g in 1 TUBE		
2	NDC:14783-990-12	12 in 1 CARTON		
2	NDC:14783-990-11	11.4 g in 1 TRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	11/26/2010	

Labeler - Ventura International, Limited (603192787)

Establishment

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

Revised: 11/2010

Ventura International, Limited