

**LBEL COULEUR LUXE ROUGE AMPLIFIER XP- 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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**COULEUR LUXE ROUGE AMPLIFIER XP**

**Active Ingredients**

Octinoxate (4.6 %), Oxybenzone (0.9 %)

**Purpose**

Sunscreen

**Uses**

Helps prevent sunburn.

**Warnings**

Stop use if skin rash occurs.

**Directions**

Apply smoothly every morning before sun exposure and as needed. Apply lipstick following the curves of natural lip line. For added definition, use with a lip pencil. Children under 6 months of age: ask a doctor. Moderate sun protection product.

**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**

Diisopropyl dimer dilinoleate, methyl hydrogenated rosinatate, isostearyl neopentanoate, castor isostearate beeswax succinate, ci 77019 (mica), ethylhexyl methoxycinnamate, hydrogenated polycyclopentadiene, polyethylene, copernicia cerifera (carnauba) wax, euphorbia cerifera (candelilla) wax, ozokerite, ethylhexyl palmitate, isododecane, paraffin, hydrogenated polyisobutene, polyglyceryl-3 diisostearate, glyceryl isostearate, isostearyl alcohol, dipalmitoyl hydroxyproline, benzophenone-3, ceramide 3, butyrospermum parkii (shea butter), beta-sitosterol, dimethicone, silica silylate, luffa cylindrica seed oil, silica, propylparaben, methylparaben, disteardimonium hectorite, ppg-26-buteth-26, peg-40 hydrogenated castor oil, polysorbate 80, parfum (fragrance), hedera helix (ivy) leaf/stem extract, trimethylsiloxysilicate, bht, tocopheryl acetate, retinyl palmitate, ascorbyl palmitate, bioflavonoids, allantoin. May contain: ci 45380:2 (red 21 lake), ci 77491, ci 77492, ci 77499 (iron oxides), ci 15850:1 (red 7 lake), ci 19140 (yellow 5 lake), ci 77891 (titanium dioxide), ci 77163 (bismuth oxychloride), talc.

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

**PR:** Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926.

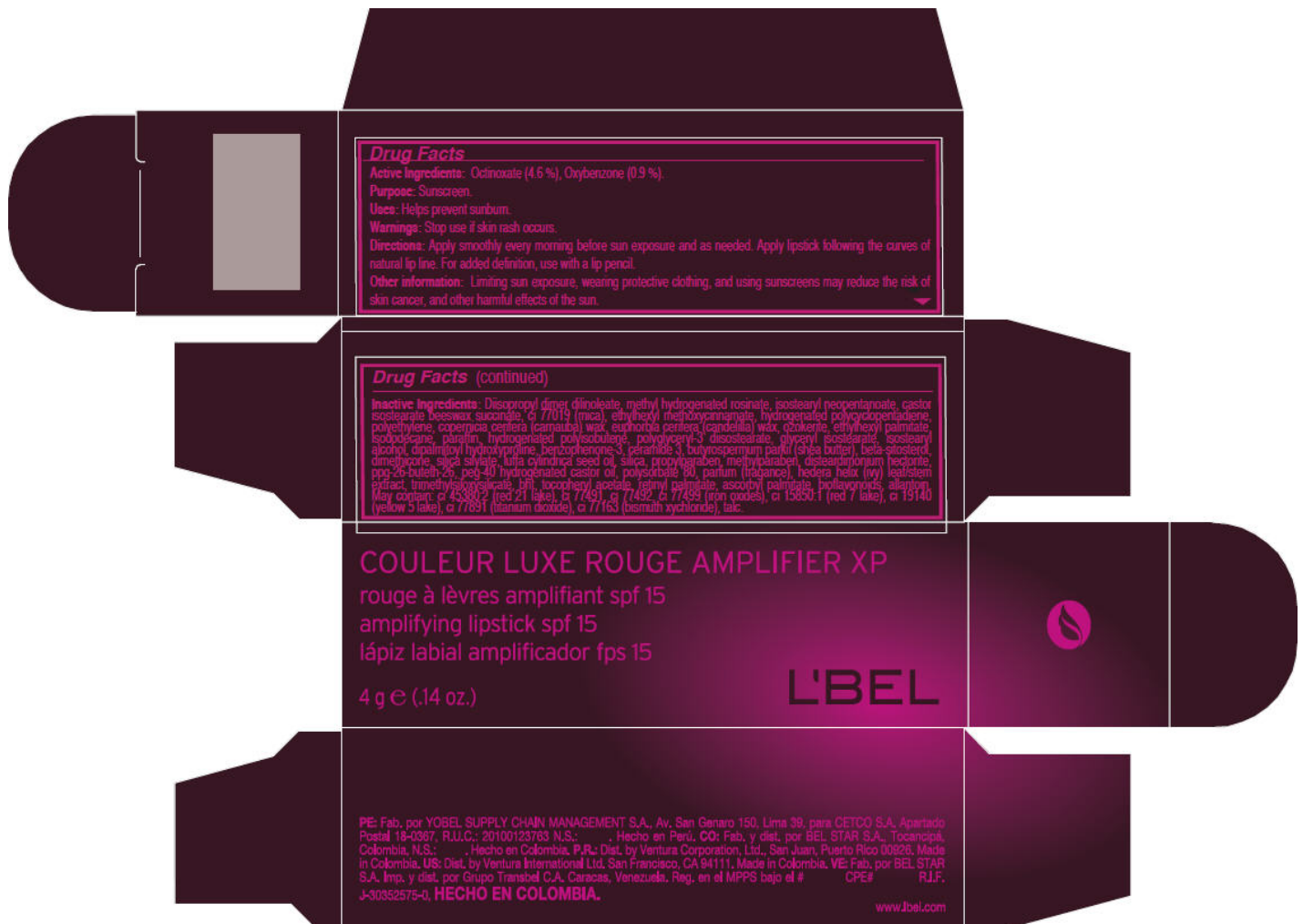
# PRINCIPAL DISPLAY PANEL - 4 g Carton

COULEUR LUXE ROUGE AMPLIFIER XP

amplifying lipstick spf 15

4 g e (.14 oz.)

L'BEL



### Drug Facts

**Active Ingredients:** Octinoxate (4.6%), Oxybenzone (0.9%)

**Purpose:** Sunscreen.

**Uses:** Helps prevent sunburn.

**Warnings:** Stop use if skin rash occurs.

**Directions:** Apply smoothly every morning 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.

### Drug Facts (continued)

**Inactive Ingredients:** Disopropyl dimethyl dilinoleate, methyl hydrogenated rosinate, isostearyl neopentanoate, castor isotriolate, beeswax, succinyl, ci 77019 (mica), ethylhexyl methoxybenzoyl, hydrogenated poly(cyclopentadiene), polyethylene, copolymer (sepiolite) carnation wax, eschscholzia persica (safflower) wax, octkerite, ethylhexyl palmitate, isododecane, paraffin, hydrogenated polyisobutylene, poly(vinyl-3) disostearate, glyceryl isostearate, isostearyl alcohol, dipalmitoyl hydroxypropylene, benzophenone-3, parahide 3, butyrospermum parkii (shea butter), beta-sitosterol, omeigalonic, silica silicate, lujia chinensis seed oil, silica, propylparaben, methylparaben, disteardipropylum, hexylene glycol, poly-40 hydrogenated castor oil, polyisobutyl 90 paraffin (triglyceride), hedera helix (ivy) leaf-stem extract, trimethylsilyl silicate, trifluoroacetyl, tetraethyl acetate, acetyl palmitate, poly(vinylpyrrolidone), aluminum. May contain: ci 45380 (red 21 lake), ci 77491, ci 77492, ci 77493 (iron oxides), ci 15850:1 (red 7 lake), ci 19140 (yellow 5 lake), ci 77891 (titanium dioxide), ci 77163 (bismuth oxychloride), talc.

## COULEUR LUXE ROUGE AMPLIFIER XP

rouge à lèvres amplifiant spf 15

amplifying lipstick spf 15

lápiz labial amplificador fps 15

4 g e (.14 oz.)

L'BEL

PE: Fab. por YOBEL SUPPLY CHAIN MANAGEMENT S.A., Av. San Gerardo 150, Lima 39, para GETCO S.A. Apartado Postal 18-0367, R.U.C.: 20100123763 N.S., Hecho en Perú. CO: Fab. y dist. por BEL STAR S.A., Tocancipá, Colombia, N.S., Hecho en Colombia. P.R.: Dist. by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926. Made in Colombia. US: Dist. by Ventura International Ltd, San Francisco, CA 94111. Made in Colombia. VE: Fab. por BEL STAR S.A. Imp. y dist. por Grupo Transbel C.A. Caracas, Venezuela. Reg. en el MPPS bajo el # CPEA R.I.F. J-30352575-0, HECHO EN COLOMBIA.

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## LBEL COULEUR LUXE ROUGE AMPLIFIER XP

octinoxate and oxybenzone lipstick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14783-081
<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	0.18 g in 4 g
<b>Oxybenzone</b> (UNII: 950OS7VE0Y) (Oxybenzone - UNII:950OS7VE0Y)	Oxybenzone	0.0036 g in 4 g

## Inactive Ingredients

Ingredient Name	Strength
<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>candelilla wax</b> (UNII: WL0328HX19)	
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>isododecane</b> (UNII: A8289P68Y2)	
<b>paraffin</b> (UNII: I9O0E3H2ZE)	
<b>isostearyl alcohol</b> (UNII: Q613OCQ44Y)	
<b>dipalmitoyl hydroxyproline</b> (UNII: E6AHA53N1H)	
<b>shea butter</b> (UNII: K49155WL9Y)	
<b>.beta.-sitosterol</b> (UNII: S347WMO6M4)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>methylparaben</b> (UNII: A218C7HI9T)	
<b>polyoxyl 40 hydrogenated castor oil</b> (UNII: 7YC686GQ8F)	
<b>polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>kalmia latifolia leaf</b> (UNII: 79N6542N18)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>vitamin a palmitate</b> (UNII: 1D1K0N0VVC)	
<b>ascorbyl palmitate</b> (UNII: QN83US2B0N)	
<b>allantoin</b> (UNII: 344S277G0Z)	
<b>D&amp;C red no. 21</b> (UNII: 08744Z6JNY)	
<b>Aluminum Oxide</b> (UNII: LMI26O6933)	
<b>ferric oxide red</b> (UNII: 1K09F3G675)	
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)	
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)	
<b>D&amp;C red no. 6</b> (UNII: 481744AI4O)	
<b>FD&amp;C yellow no. 5</b> (UNII: I753WB2F1M)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	
<b>talc</b> (UNII: 7SEV7J4RIU)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-081-62	1 in 1 BOX		
1	NDC:14783-081-61	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)