

**LBEL PROTEGE EXPERT- octinoxate, octisalate, oxybenzone, and titanium dioxide lotion  
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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**L'BEL  
PROTEGE  
EXPERT  
moisturizing body  
protector lotion  
SPF 15**

***Drug Facts***

**Active Ingredients**

Octinoxate 7.5%,  
Octisalate 5%,  
Oxybenzone 6%,  
Titanium dioxide 2.34%

**Purpose**

Sunscreen

**Uses**

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Provides moderate protection against sunburn.
- Retains SPF after 40 minutes of activity in the water

**Warnings**

**For external use only.**

**When using this product** keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor if** rash or irritation develops and lasts.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply liberally before sun exposure and as needed

**Other information**

- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

**Inactive ingredients**

Aqua (water), dicaprylyl carbonate, c12-15 alkyl benzoate, vp/eicosene copolymer, methyl methacrylate crosspolymer, cyclopentasiloxane, dimethicone, cetearyl alcohol, sorbitan stearate, cyclohexasiloxane, glyceryl stearate, potassium cetyl phosphate, tocopheryl acetate, trimethylsiloxysilicate, phenoxyethanol, silica, methicone, cetareth-20, methylparaben, xanthan gum, mannitol, parfum (fragrance), propylparaben, butylparaben, ethylparaben, isobutylparaben, arginine, cyclodextrin, dextrin, faex extract (yeast extract), histidine hydrochloride (histidine hci), pisum sativum extract (pisum sativum (pea) extract), acetyl tyrosine, disodium succinate, khaya senegalensis bark extract, nicotinamide adenine dinucleotide, pyridoxine hci, aspartic acid

**PRINCIPAL DISPLAY PANEL - 180 ml Bottle Carton**

**L'BEL**

PROTÈGE  
EXPERT

moisturizing body  
protector lotion  
SPF 15

WATER RESISTANT

180 ml e (6.3 fl.oz.)

**UVB SPF**

**15**

Moderate  
Protection

UVA

**PA ++**



• HYPOALLERGENIC  
• DERMATOLOGICALLY TESTED

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L'BEL

PROTÈGE  
EXPERT

moisturizing body  
protector lotion  
SPF 15

loción protectora  
hidratante para cuerpo  
FPS 15

WATER RESISTANT  
RESISTENTE AL AGUA

180 ml e (6.3 fl.oz.)

UVA	UVA
<b>15</b>	PA ++
Moderate Protection	

octinoxate, octisalate, oxybenzone, and titanium dioxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14783-301
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	.075 g in 1 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	.05 g in 1 mL
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	.06 g in 1 mL
<b>Titanium dioxide</b> (UNII: 15FIX9V2JP) (Titanium dioxide - UNII:15FIX9V2JP)	Titanium dioxide	.0234 g in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>water</b> (UNII: 059QF0K00R)	
<b>dicaprylyl carbonate</b> (UNII: 609A3V1SUA)	
<b>alkyl (c12-15) benzoate</b> (UNII: A9EJ3J61HQ)	
<b>trolamine</b> (UNII: 9O3K93S3TK)	
<b>cyclomethicone 5</b> (UNII: 0THT5PCI0R)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>sorbitan monostearate</b> (UNII: NVZ4I0H58X)	
<b>cyclomethicone 6</b> (UNII: XHK3U310BA)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>potassium cetyl phosphate</b> (UNII: 03KCY6P7UT)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>polyoxyl 20 cetostearyl ether</b> (UNII: YRC528SWUY)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>mannitol</b> (UNII: 3OWL53L36A)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>butylparaben</b> (UNII: 3QPII03FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>arginine</b> (UNII: 94ZLA3W45F)	
<b>yeast</b> (UNII: 3NY3SM6B8U)	
<b>histidine monohydrochloride</b> (UNII: 1D5Q932XM6)	
<b>pea</b> (UNII: W4X7H8GYFM)	
<b>sodium succinate anhydrous</b> (UNII: V8ZGC8ISR3)	
<b>khaya senegalensis bark</b> (UNII: 1S7EDA839L)	
<b>nadide</b> (UNII: 0U46U6E8UK)	
<b>pyridoxine hydrochloride</b> (UNII: 68Y4CF58BV)	
<b>aspartic acid</b> (UNII: 30KYC7MIAD)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-301-02	1 in 1 BOX		
1	NDC:14783-301-01	180 mL in 1 BOTTLE		
2	NDC:14783-301-04	1 in 1 BOX		
2	NDC:14783-301-03	10 mL in 1 TUBE		
3	NDC:14783-301-06	1 in 1 BOX		
3	NDC:14783-301-05	5 mL in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	04/19/2011	

**Labeler** - Ventura International Ltd. (603192787)

## Establishment

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

Revised: 2/2011

Ventura International Ltd.