

**LBEL UV DEFENSE 365- homosalate, octinoxate, octisalate, oxybenzone, titanium dioxide, and zinc oxide lotion**

**Ventura Corporation Ltd. (San Juan, P.R)**

*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  
UV DÉFENSE 365**

***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
Homosalate (5 %)	Sunscreen
Octinoxate (7 %)	Sunscreen
Octisalate (5 %)	Sunscreen
Oxybenzone (4 %)	Sunscreen
Titanium Dioxide (6.24%)	Sunscreen
Zinc Oxide (3.88%)	Sunscreen

**Uses**

- Helps prevent sunburn.
- higher SPF gives more sunburn protection

**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 and 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 smoothly every morning before sun exposure and as needed.

**Other information**

- High sun protection product.
- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin cancer, and other harmful effects of the sun.
- Apply the product with your fingertips. Use every morning before exposure to UVA and UVB radiation or whenever needed.

**Inactive ingredients**

Aqua (water), dicaprylyl carbonate, propylheptyl caprylate, glyceryl stearate, potassium cetyl phosphate, alcohol denat., cyclohexasiloxane, polymethylsilsesquioxane, glycerin, sorbitan stearate, bis-ethylhexyl hydroxydimethoxy benzylmalonate, dimethicone, tocopheryl acetate, cetareth-20, silica, methicone, cetaryl alcohol, cetareth-12, cetyl palmitate, peg-8, propylene glycol, phenoxyethanol,

methylparaben, ambrosia peruviana leaf extract, xanthan gum, caprylyl glycol, mica, propylparaben, triethoxycaprylylsilane, butylene glycol, helianthus annuus (sunflower) seed extract, ppg-1-peg-9-lauryl glycol ether, chlorphenesin, cyclopentasiloxane, heder helix (ivy) leaf/stem extract, phytic acid, sodium polyacrylate.

Dist. by Ventura Corporation, Ltd, San Juan, Puerto Rico 00926.

**PRINCIPAL DISPLAY PANEL - 30 ml Bottle Carton**

**L'BEL**

UV DÉFENSE 365

oil-free daily protective  
facial lotion SPF 50

**UVB SPF 50**

**UVA PA +++**

30 ml e (1 fl.oz.)

www.lbel.com

L'BEL

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**Inactive ingredients** aqua (water), dicaprylyl carbonate, propylheptyl caprylate, glyceryl stearate, potassium cetyl phosphate, alcohol denat., cyclohexasiloxane, polymethylsilsesquioxane, glycerin, sorbitan stearate, bisethylhexyl

**Drug Facts (continued)**

hydroxydimethoxy benzylmalonate, dimethicone, tocopheryl acetate, silica, methicone, peg-8, cetareth-12, cetareth-20, propylene glycol, phenoxyethanol, methylparaben, ambrosia peruviana leaf extract, cetearyl alcohol, cetyl palmitate, xanthan gum, caprylyl glycol, mica, propylparaben, butylene glycol, helianthus annuus seed extract (helianthus annuus (sunflower) seed extract), ppg-1-peg-9-lauryl glycol ether, chlorphenesin, triethoxycaprylylsilane, cyclopentasiloxane, heder helix extract (hedera helix (ivy) leaf/stem extract), phytic acid, sodium polyacrylate.

US: Dist. by Ventura International Ltd, San Francisco, CA 94111. P.R.: Dist. by Ventura Corporation, Ltd, San Juan, Puerto Rico 00926.

MADE IN FRANCE

UV DÉFENSE 365

oil-free daily protective facial lotion SPF 50

UVB SPF 50  
UVA PA +++

30 ml e (1 fl.oz.)

## LBEL UV DEFENSE 365

homosalate, octinoxate, octisalate, oxybenzone, titanium dioxide, and zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-402
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Homosalate</b> (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	0.05 g in 1 mL
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.05 g in 1 mL
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.04 g in 1 mL
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0624 g in 1 mL
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.0388 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>water</b> (UNII: 059QF0K00R)	
<b>dicaprylyl carbonate</b> (UNII: 609A3V1SUA)	
<b>propylheptyl caprylate</b> (UNII: 991Z19V2OD)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>potassium cetyl phosphate</b> (UNII: 03KCY6P7UT)	
<b>cyclomethicone 6</b> (UNII: XHK3U310BA)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>sorbitan monostearate</b> (UNII: NVZ4I0H58X)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>polyoxyl 20 cetostearyl ether</b> (UNII: YRC528SWUY)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetareth-12</b> (UNII: 7V4MR24V5P)	
<b>cetyl palmitate</b> (UNII: 5ZA2S6B08X)	
<b>polyethylene glycol 400</b> (UNII: B697894SGQ)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>ambrosia peruviana leaf</b> (UNII: 458F79CGBF)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>caprylyl glycol</b> (UNII: 00YIU5438U)	
<b>mica</b> (UNII: V8A1AW0880)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>triethoxycaprylylsilane</b> (UNII: LDC331P08E)	
<b>butylene glycol</b> (UNII: 3XUS85K0RA)	

<b>sunflower seed</b> (UNII: R9N3379M4Z)	
<b>chlorphenesin</b> (UNII: I670DAL4SZ)	
<b>cyclomethicone 5</b> (UNII: 0THT5PCI0R)	
<b>hedera helix top</b> (UNII: 379040L9FW)	
<b>phytic acid</b> (UNII: 7IGF0S7R8I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-402-02	1 in 1 BOX		
1	NDC:13537-402-01	30 mL in 1 BOTTLE		
2	NDC:13537-402-04	1 in 1 BOX		
2	NDC:13537-402-03	3 mL in 1 BOTTLE		
3	NDC:13537-402-05	1 mL in 1 PACKET		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/29/2011	

**Labeler** - Ventura Corporation Ltd. (San Juan, P.R) (602751344)

### Establishment

Name	Address	ID/FEI	Business Operations
MF Productions Saumur		266769145	MANUFACTURE

Revised: 8/2011

Ventura Corporation Ltd. (San Juan, P.R)