

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

Ventura International 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.

**L'BEL
UV DÉFENSE 365**

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
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, bisethylhexyl hydroxydimethoxy benzylmalonate, dimethicone, tocopheryl acetate, silica, methicone, peg-8,

ceteareth-12, ceteareth-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.

Dist. by Ventura International Ltd, San Francisco, CA 94111.

PRINCIPAL DISPLAY PANEL - 30 ml 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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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, hederia helix extract (hederia 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

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-094
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-094-02	1 in 1 BOX		
1	NDC:14783-094-01	30 mL in 1 BOTTLE		
2	NDC:14783-094-04	1 in 1 BOX		
2	NDC:14783-094-03	3 mL in 1 BOTTLE		
3	NDC:14783-094-05	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 International Ltd. (San Juan, P.R) (603192787)

Establishment

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

Revised: 8/2011

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