

LBEL DEFENSE 365 DAILY PROTECTIVE SPF 50- octinoxate, titanium dioxide, homosalate, octisalate, oxybenzone, and zinc oxide 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.

L'BEL DÉFENSE 365 OIL-FREE DAILY PROTECTIVE FACIAL LOTION SPF 50

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Homosalate (5.00%)	Sunscreen
Octinoxate (7.00%)	Sunscreen
Octisalate (5.00%)	Sunscreen
Oxybenzone (4.00%)	Sunscreen
Titanium dioxide (6.24%)	Sunscreen
Zinc oxide (3.92%)	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.
- **For external use only.**
- **Do not use** on damaged or broken skin.
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor if** rash occurs.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive ingredients

Water, dicaprylyl carbonate, propylheptyl caprylate, glyceryl stearate, potassium cetyl phosphate,

alcohol denat., cyclohexasiloxane, polymethylsilsesquioxane, glycerin, sorbitan stearate, bis-ethylhexyl 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, propylparaben, chlorphenesin, butylene glycol, helianthus annuus (sunflower) seed extract, mica, ppg-1-peg-9 lauryl glycol ether, triethoxycaprylylsilane, cyclopentasiloxane, hedera helix (ivy) leaf/stem extract, phytic acid, sodium polyacrylate.

US: Dist. by Ventura Int Ltd. DBA
Belcorp USA, San Francisco, CA
94111.

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box

L'BEL

DÉFENSE 365

oil-free daily protective
facial lotion SPF 50

SPF 50

30 ml e (1 fl.oz.)

www.lbel.com

L'BEL

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Drug Facts
(continued)

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

US: Dist. by Ventura Int Ltd. DBA Belcorp USA, San Francisco, CA 94111. Made in Colombia. P.R.: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

Formulated in France
Made in Colombia

DÉFENSE 365

oil-free daily protective
facial lotion SPF 50

SPF 50

30 ml e (1 fl.oz.)

LBEL DEFENSE 365 DAILY PROTECTIVE SPF 50

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-901
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.062 g in 1 mL
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	0.05 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
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.039 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
dicaprylyl carbonate (UNII: 609A3V1SUA)	
propylheptyl caprylate (UNII: 991Z19V2OD)	
glyceryl monostearate (UNII: 230OU9XXE4)	
potassium cetyl phosphate (UNII: 03KCY6P7UT)	
alcohol (UNII: 3K9958V90M)	
cyclomethicone 6 (UNII: XHK3U310BA)	
glycerin (UNII: PDC6A3C0OX)	
sorbitan monostearate (UNII: NVZ4I0H58X)	
bis-ethylhexyl hydroxydimethoxy benzylmalonate (UNII: 7D4Q5YJ8NV)	
dimethicone (UNII: 92RU3N3Y1O)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
polyethylene glycol 400 (UNII: B697894SGQ)	
cetareth-12 (UNII: 7V4MR24V5P)	
polyoxyl 20 cetostearyl ether (UNII: YRC528SWUY)	
propylene glycol (UNII: 6DC9Q167V3)	
phenoxyethanol (UNII: HIE492ZZ3T)	
methylparaben (UNII: A2I8C7HI9T)	
ambrosia peruviana leaf (UNII: 458F79CGBF)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetyl palmitate (UNII: 5ZA2S6B08X)	
xanthan gum (UNII: TTV12P4NEE)	
caprylyl glycol (UNII: 00YIU5438U)	
propylparaben (UNII: Z8IX2SC1OH)	

chlorphenesin (UNII: I670DAL4SZ)	
butylene glycol (UNII: 3XUS85K0RA)	
sunflower seed (UNII: R9N3379M4Z)	
mica (UNII: V8A1AW0880)	
ppg-1-peg-9 lauryl glycol ether (UNII: 5R8J43K25L)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
hedera helix leaf (UNII: ZP9XFG71A7)	
fytic acid (UNII: 7IGF0S7R8I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-901-02	1 in 1 BOX		
1	NDC:14783-901-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	10/14/2014	

Labeler - Ventura International LTD (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-901)

Revised: 10/2014

Ventura International LTD