

**LBEL DEFENSE 365 OIL-FREE DAILY PROTECTIVE FACIAL SPF 50- homosalate, octinoxate, octisalate, oxybenzone, titanium dioxide, and zinc oxide lotion  
Ventura Corporation 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 DÉFENSE 365 oil-free daily protective facial lotion SPF 50**

***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
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 BENZYL MALONATE, 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, 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.

Dist. by Bentura Corp, Ltd., San Juan, Puerto Rico 00926.

**PRINCIPAL DISPLAY PANEL - 30 ml Tube Box**

**L'BEL**

DÉFENSE 365

oil-free daily protective

**facial lotion SPF 50**

**SPF 50**

30 ml e (1 fl.oz.)

www.l'bel.com

L'BEL

**Drug Facts**

**Active Ingredients Purpose**

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**

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**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, ▶

**Drug Facts (continued)**

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, heder helix (ivy) leaf/stem extract, phytic acid, sodium polyacrylate,

DÉFENSE 365

oil-free daily protective facial lotion SPF 50

SPF 50

30 ml e (1 fl.oz.)

U.S.A.: Dist. by Ventura Int Ltd. DBA Belcorp USA, Miami, FL 33126 Made in Colombia **PUERTO RICO:** Dist. by Ventura Corp. Ltd., San Juan, Puerto Rico 00926, Made in Colombia

Formulated in France

# LBEL DEFENSE 365 OIL-FREE DAILY PROTECTIVE FACIAL SPF 50

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

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-177
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	0.0392 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)	
ALCOHOL (UNII: 3K9958V90M)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYL MALONATE (UNII: 7D4Q5YJ8NV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
AMBROSIA PERUVIANA LEAF (UNII: 458F79CGBF)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>SUNFLOWER SEED</b> (UNII: R9N3379M4Z)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>PPG-1-PEG-9 LAURYL GLYCOL ETHER</b> (UNII: 5R8J43K25L)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THI5PCI0R)	
<b>HEDERA HELIX LEAF</b> (UNII: ZP9XFG71A7)	
<b>FYTIC ACID</b> (UNII: 7IGF0S7R8I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-177-02	1 in 1 BOX	10/31/2016	
1	NDC:13537-177-01	30 mL in 1 TUBE; 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	10/31/2016	

**Labeler** - Ventura Corporation LTD (602751344)

### Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-177)

Revised: 11/2016

Ventura Corporation LTD