

**LBEL DEFENSE 365 DAILY PROTECTIVE FACIAL SPF 50 - homosalate, octinoxate, octisalate, oxybenzone, titanium dioxide, 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 DEFENSE 365 Oil-Free Daily Protective Facial Lotion SPF 50**

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**Active Ingredients**

Homosalate (5%)  
Octinoxate (7.0%)  
Octisalate (5.0%)  
Oxybenzone (4.0%)  
Titanium Dioxide (6.24%)  
Zinc Oxide (3.92%)

**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**

Aqua (Water), dicaprylyl carbonate, propylheptyl caprylate, glyceryl stearate, potassium cetyl phosphate, alcohol denat., cyclohexasiloxane, polymethylsilsesquioxane, glycerin, sorbitan stearate, bis(2-ethylhexyl hydroxydimethoxy benzylmalonate), dimethicone, tocopheryl acetate, silica, methicone, peg-8, cetareth-12, cetareth-20, propylene glycol, phenoxyethanol, methylparaben, ambrosia peruviana leaf extract, cetaryl 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, chlorophenesin, triethoxycaprylylsilane, cyclopentasiloxane, heder helix leaf/stem extract (heder helix (ivy) leaf/stem extract), phytic acid, sodium polyacrylate.

**Purpose**

Sunscreen

L'BEL DEFENSE 365 oil-free protective facial lotion SPF 50 30ml e (1 fl. oz.)

US: Dist. by Ventural Internationa Ltd. DBA Bellcorp USA, San Francisco, CA 94111

P.R. Dist. by Ventura Corporation Ltd., San Juan, Puerto Rico 00926 MADE IN FRANCE

**L'BEL DEFENSE 365 Oil-Free Daily Protective Facial Lotion SPF 50**

# L'BEL

## DÉFENSE 365

oil-free daily  
protective facial  
lotion SPF 50

SPF  
50

30 ml e (1 fl.oz.)

### SHAKE BEFORE USING

**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  
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on** damaged or broken  
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eyes. Rinse with water  
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reach of children.** If  
swallowed, get medical  
help or contact a Poison  
Control Center right  
away.

**ACTIVE INGREDIENTS:** HOMO-  
SALATE (5 %), OCTINOXATE (7 %),  
OCTISALATE (5 %), OXYBENZONE  
(4 %), TITANIUM DIOXIDE (6.24 %),  
ZINC OXIDE (3.92%).

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**Drug Facts**

**Active Ingredients Purpose**

Homosalate (5%)  
Octinoxate (7.0%)  
Octisalate (5.0%)  
Oxybenzone (4.0%)  
Titanium dioxide (6.24%)  
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**

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, silica, methicone, ▶

**Drug Facts**  
(continued)

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

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**MADE IN FRANCE**

**L'BEL**

**DÉFENSE 365**

oil-free daily protective  
facial lotion SPF 50

**SPF 50**

**30 ml e (1 fl.oz.)**

# LBEL DEFENSE 365 DAILY PROTECTIVE FACIAL SPF 50

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

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43596-0001
<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	5 mL in 100 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 mL in 100 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 mL in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	4 mL in 100 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	6.24 mL in 100 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.92 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<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>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58 X)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>CETEARETH-12</b> (UNII: 7V4MR24V5P)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	

AMBROSIA PERUVIANA LEAF (UNII: 458F79CGBF)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETYL PALMITATE (UNII: 5ZA2S6B08X)
XANTHAN GUM (UNII: TTV12P4NEE)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
MICA (UNII: V8A1AW0880)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)
CHLORPHENESIN (UNII: I670DAL4SZ)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)
HEDERA HELIX LEAF (UNII: ZP9XFG71A7)
FYTIC ACID (UNII: 7IGF0S7R8I)
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0001-0	1 mL in 1 POUCH		
2	NDC:43596-0001-1	3 mL in 1 TUBE		
3	NDC:43596-0001-2	30 mL in 1 JAR		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	03/25/2012		

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

Establishment			
Name	Address	ID/FEI	Business Operations
MF Productions		266769145	manufacture