

LBEL DEFENSE 365 DAILY PROTECTIVE FACIAL SPF 50 - homosalate, octinoxate, octisalate, oxybenzone, titanium dioxide, 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 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, ceteryl 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

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SHAKE BEFORE USING

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**WARNINGS: Skin
Cancer / Skin Aging**

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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

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Warnings ■ Skin Cancer / Skin

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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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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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43455-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 mL in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 mL in 100 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	4 mL in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	6.24 mL in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.92 mL in 100 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: NVZ4I0H58 X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

AMBROSIA PERUVIANA LEAF (UNII: 458F79CGBF)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
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:43455-0001-0	1 mL in 1 POUCH		
2	NDC:43455-0001-1	3 mL in 1 TUBE		
3	NDC:43455-0001-2	30 mL in 1 JAR		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	03/28/2012		

Labeler - Ventura International, LTD (603192787)

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