LIFECELL BB CREAM HYDRATING ANTI-OXIDANT BEAUTY BALM BROAD SPECTRUM SPF 30 LIGHT- octinoxate and zinc oxide lotion Prime Enterprises, Inc.

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.

Active ingredients

Octinoxate 3% and Zinc Oxide 3%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use Ion 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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
- limit time in the sun, especially from 10 a.m. 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor.

Inactive Ingrediets:

Aloe Barbadensis Leaf Juice, Bentonite, Camellia Sinensis (Green Tea) Leaf Extract, Caramel, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Cholecalciferol, Cyclohexasiloxane, Cyclopentasiloxane, Disodium EDTA, DMDM Hydantoin, Hexyl Laurate, Hydrogenated Castor Oil,

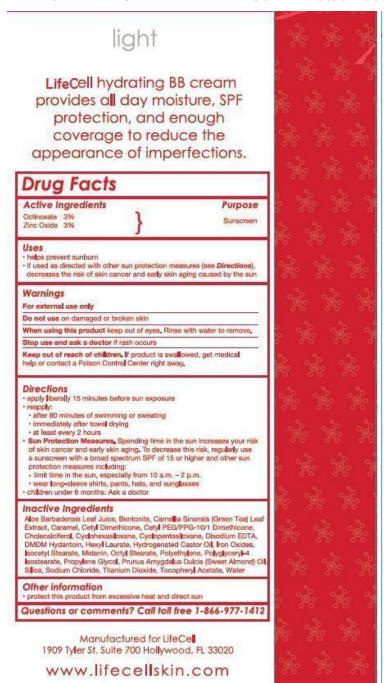
Iron Oxides, Isocetyl Stearate, Melanin, Octyl Stearate, Polyethylene, Polyglyceryl-4 Isostearate, Propylene Glycol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Silica, Sodium Chloride, Titanium Dioxide, Tocopheryl Acetate, Water

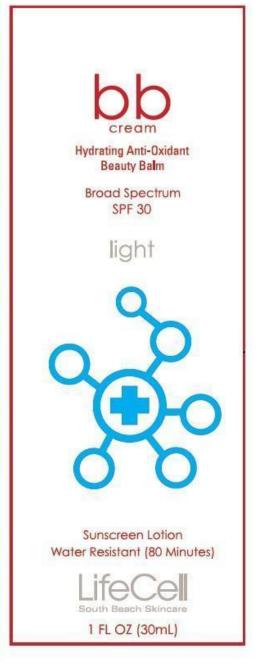
Other information

• protect this product from excessive heat and direct sun

Questions or comments? Call toll free 1-866-977-1412

PRINCIPAL DISPLAY PANEL - 30mL Bottle Label





Hydrating Anti-Oxidant Beauty Balm

Broad Spectrum

SPF 30

light

Sunscreen Lotion

Water Resistant (80 Minutes)

LifeCell

South Beach Skincare

1 FL OZ (30mL)

LIFECELL BB CREAM HYDRATING ANTI-OXIDANT BEAUTY BALM BROAD SPECTRUM SPF 30 LIGHT

octinoxate and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0182
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	29.19 mg in 1 mL		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	29.19 mg in 1 mL		

Inactive Ingredients				
Ingredient Name	Strength			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
BENTO NITE (UNII: A3N5ZCN45C)				
CARAMEL (UNII: T9D99G2B1R)				
CETYL DIMETHICO NE 150 (UNII: 5L694Y0T22)				
CETYL PEG/PPG-10/1 DIMETHICO NE (HLB 2) (UNII: V2W71V8T0X)				
CHOLECALCIFEROL (UNII: 1C6V77QF41)				
CYCLOMETHICONE (UNII: NMQ347994Z)				
CYCLOMETHICONE 6 (UNII: XHK3U310BA)				
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)				
DMDM HYDANTO IN (UNII: BYR0546 TOW)				
HEXYL LAURATE (UNII: 4CG9F9W01Q)				
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)				

MELAMINE (UNII: N3GP2YSD88) O CTYL STEARATE (UNII: 772Y4UFC8B) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) GREEN TEA LEAF (UNII: W2ZU1RY8B0)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7) PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
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CREEN TEAL FAE (UNII: W271/1RV8R0)
GREEN TEN DEAF (CIVIL W2201K10B0)
ALMOND OIL (UNII: 66YXD4DKO9)
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)
ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)
WATER (UNII: 059QF0KO0R)

Product Characteristics			
Color	bro wn	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Pa	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N	NDC:58443-0182-3	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/16/20 14	

Marketing Info	rmation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	0 1/16/20 14	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishmen	t		
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		10 19 46 0 28	label(58443-0182), pack(58443-0182), manufacture(58443-0182), analysis(58443-0182)

Revised: 1/2020 Prime Enterprises, Inc.