

LIFECCELL BB CREAM HYDRATING ANTI-OXIDANT BEAUTY BALM BROAD SPECTRUM SPF 30 MEDIUM- 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 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 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 Ingredients:

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

medium

LifeCell hydrating BB cream provides all day moisture, SPF protection, and enough coverage to reduce the appearance of imperfections.

Drug Facts	
Active Ingredients	Purpose
Octinoxate 8% Zinc Oxide 3%	Sunscreen
Uses	
<ul style="list-style-type: none"> • helps prevent sunburn • If used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun 	
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Other information	
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Questions or comments? Call toll free 1-866-977-1412	

Manufactured for LifeCell
1909 Tyler St. Suite 700 Hollywood, FL 33020

www.lifecellskin.com

bb

cream

Hydrating Anti-Oxidant
Beauty Balm

Broad Spectrum
SPF 30

medium



Sunscreen Lotion
Water Resistant (80 Minutes)

LifeCell

South Beach Skincare

1 FL OZ (30mL)

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cream

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octinoxate and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0183
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	29.4 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	29.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENTONITE (UNII: A3N5ZCN45C)	
CARAMEL (UNII: T9D99G2B1R)	
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	

FERRIC OXIDE RED (UNII: 1K09F3G675)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
MELAMINE (UNII: N3GP2YSD88)	
OCTYL STEARATE (UNII: 772Y4UFC8B)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALMOND OIL (UNII: 66YXD4DKO9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0183-3	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/13/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0183) , pack(58443-0183) , manufacture(58443-0183) , analysis(58443-0183)