

LIFECCELL BROAD SPECTRUM SPF 30 MINERAL- octinoxate, zinc oxide cream
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.

LifeCell Hydrating Antioxidant Medium BB Cream Broad Spectrum SPF 30

Active ingredients

Octinoxate 3 %

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 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

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 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-sleeved 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, Ethylhexyl Stearate, Hexyl Laurate, Hydrogenated Castor Oil, Isocetyl Stearate, Melanin, Polyethylene, Polyglyceryl-4 Isostearate, Propylene Glycol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Silica, Sodium Chloride, Titanium Dioxide, Tocopheryl Acetate, Triethoxycaprylylsilane, Water, Iron Oxides

Other information

- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-866-978-5848

LifeCell Hydrating Antioxidant Medium BB Cream Broad Spectrum SPF 30 - 50 mL

Drug Facts	
Active Ingredients	Purpose
Octinoxate 3% Zinc Oxide 3%	Sunscreen
Uses	
<ul style="list-style-type: none"> 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	
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Inactive Ingredients	
Aloe Barbados 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, Triethoxycaprylylsilane, Water	
Other information	
<ul style="list-style-type: none"> protect this product from excessive heat and direct sun 	
Questions or comments?	
<ul style="list-style-type: none"> Call toll free 1-866-978-5848 	

**HYDRATING
ANTIOXIDANT
BB CREAM**

Broad Spectrum
SPF 30

Water Resistant
(80 Minutes)

LIFECELL



MEDIUM

1.7 FL OZ (50mL)

**YOUTHFUL SKIN
AT ANY AGE**

LifeCelle BB Cream provides all-day hydration, Broad Spectrum SPF 30 protection, and enough coverage to reduce the appearance of imperfections.

**SUITABLE FOR
ALL SKIN TYPES**

www.lifecellskincare.com

**Dermatologist Tested
Hypoallergenic**

DISTRIBUTED BY LIFECELL[®]
HOLLYWOOD, FL 33020
MANUFACTURED IN USA
PLEASE RECYCLE

Hypoallergenic
Dermatologist Tested

 

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LIFECCELL BROAD SPECTRUM SPF 30 MINERAL

octinoxate, zinc oxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58443-0426

Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	30.03 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	30.03 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
ALMOND OIL (UNII: 66YXD4DKO9)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)			
BENTONITE (UNII: A3N5ZCN45C)			
DMDM HYDANTOIN (UNII: BYR0546TOW)			
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)			
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
WATER (UNII: 059QF0KO0R)			
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)			
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)			
HEXYL LAURATE (UNII: 4CG9F9W01Q)			
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
CHOLECALCIFEROL (UNII: 1C6V77QF41)			
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)			
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)			
ISOCETYL STEARATE (UNII: 3RJ7186O9W)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
CAMEL (UNII: T9D99G2B1R)			
CYCLOMETHICONE 6 (UNII: XHK3U310BA)			
MELANIN SYNTHETIC (TYROSINE, PEROXIDE) (UNII: O0CV1RMR44)			
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)			
HYDROGENATED CASTOR OIL (UNII: Z F94AP8MEY)			
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)			
D&C BLACK NO. 2 (UNII: 4XYU5U00C4)			
Product Characteristics			
Color	brown (Nude)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0426-3	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/23/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/23/2015	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0426) , manufacture(58443-0426) , label(58443-0426) , analysis(58443-0426)

Revised: 9/2021

Prime Enterprises Inc.