LIFECELL BROAD SPECTRUM SPF 50 BB SHEER- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone 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 BB Cream Broad Spectrum SPF 50

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octosalate 5%

Octocrylene 2.75%

Oxybenzone 2%

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 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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Butylphthalimide, Cetyl Alcohol, Disodium EDTA, Glycyrrhiza Glabra (Licorice) Root Extract, Isopropylphthalimide, Methylisothiazolinone, Phenoxyethanol, Phenyl Trimethicone, Polyethylene, Potassium Cetyl Phosphate, Potassium Hydroxide, Propylene Glycol, Silica, Stearyl Alcohol, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Ubiquinone, Undecylcrylene Dimethicone, Water

Other Information

• protect this product from excessive heat and direct sun

Questions or comments?

• Call toll free 1-866-978-5848

Lifecell BB Cream Broad Spectrum SPF 30



LIFECELL BROAD SPECTRUM SPF 50 BB SHEER

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0194
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	27.5 mg in 1 mL	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	50 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	20 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
STEARYL ALCOHOL (UNII: 2KR8914H1Y)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
UBIDECARENO NE (UNII: EJ27X76 M46)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
PHENYL TRIMETHICO NE (UNII: DR0 K5NOJ4R)			
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)			
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)			
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)			
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)			
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)			
POTASSIUM HYDRO XIDE (UNII: WZH3C48M4T)			
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)			
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)			

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0194-3	50 mL in 1 TUBE; Type 0: Not a Combination Product	10/05/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/05/2015	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		10 19 46 0 28	pack(58443-0194), manufacture(58443-0194), label(58443-0194)

Revised: 1/2020 Prime Enterprises Inc.