

ALOE UP PRO SPF 30 SUNSCREEN- avobenzone, homosalate, octisalate, and octocrylene 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.

Aloe Up Pro SPF 30 Sunscreen Lotion

Active Ingredients

Avobenzone 3.0%

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 3.5%

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

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 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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Aluminum Starch Octenylsuccinate, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf

Extract, Carbomer, Iodopropynyl Butylcarbamate, Isodecyl Neopentanoate, Isopropylphthalimide, Methylisothiazolinone, PEG-8, Phenoxyethanol, Polyethylene, Polysorbate 20, Propanediol, Sorbitol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethanolamine, Trisodium Ethylenediamine Disuccinate, Water

Other Information

- protect this product from excessive heat and direct sun

Questions or Comments?

Call toll free 1-800-950-2563

Aloe Up Pro SPF 30 Sunscreen



Pro
SPF 30

PERFORMANCE
SUNSCREEN LOTION

ALOE BASED
DRY FORMULA

ABSORBS QUICKLY

OXYBENZONE &
PARABEN-FREE

WATER RESISTANT
(80 MINUTES)

UVA/UVB
BROAD SPECTRUM
SPF 30

4 FL OZ (118 mL)

Drug Facts

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Inactive Ingredients

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ANTIOXIDANT INFUSED SUNSCREEN FOR ATHLETES BASED WITH 35% ALOE VERA GEL. BIODEGRADABLE AND FRAGRANCE FREE. FORMULATED WITHOUT THE USE OF PARABENS, ALCOHOL AND OXYBENZONE.



Complies with ASTM 2804:2012

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ALOE UP PRO SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate, and octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0230
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	35 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
COCOA BUTTER (UNII: 512OYT1CRR)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
ISOPROPYLPHthalimide (UNII: 1J1MM83329)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALLANTOIN (UNII: 344S277G0Z)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
SORBITOL (UNII: 506T60A25R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
N-BUTYLPHthalimide (UNII: 5TH1DKT35E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
PROPANEDIOL (UNII: 5965N8W85T)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0230-3	118 mL in 1 TUBE; Type 0: Not a Combination Product	04/07/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/07/2016	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0230) , manufacture(58443-0230) , label(58443-0230) , analysis(58443-0230)

Revised: 1/2020

Prime Enterprises Inc.