

ALOE UP BROAD SPECTRUM 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 Coco-Mango 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, Ethylhexylglycerin, Fragrance, Isodecyl Neopentanoate, Isopropylphthalimide, PEG-8, Phenoxyethanol, Polyethylene, Polysorbate 20, Propanediol, Sodium Hydroxide, Sorbitol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, 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 • www.aloeup.com

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BROAD SPECTRUM
SPF 30

4 FL OZ (118 mL)

Drug Facts

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BASED WITH 35% PURE ALOE VERA GEL • REEF FRIENDLY
COCONUT MANGO FRAGRANCE • ALCOHOL & MINERAL OIL FREE
PHTHALATE FREE

Infused with
ALOE VERA GEL,
COCOA BUTTER,
GREEN TEA EXTRACT
& VITAMIN E



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ALOE UP BROAD SPECTRUM SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate, and octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0631
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 g in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	35 g in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 g in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
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: I9PJ006294)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
PROPANEDIOL (UNII: 5965N8W85T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
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:58443-0631-3	118 mL in 1 TUBE; Type 0: Not a Combination Product	08/04/2023	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	M020	08/04/2023	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	manufacture(58443-0631) , label(58443-0631) , pack(58443-0631) , analysis(58443-0631)

Revised: 8/2023

Prime Enterprises Inc.