

**ALOE UP BROAD SPECTRUM SPF 50 SUNSCREEN- octisalate, avobenzone, homosalate, 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 Broad Spectrum SPF 50 Sunscreen Lotion

Active Ingredients

Avobenzone 3%

Homosalate 15%

Octisalate 5%

Octocrylene 10%

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 value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10am-2pm
 - wear long sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

INACTIVE INGREDIENTS

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Aluminum Starch Octenylsuccinate, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Ethylhexylglycerin, Fragrance, Isodecyl Neopentanoate, Phenoxyethanol, Polyethylene, Polysorbate 20, Propanediol, Sodium Hydroxide, Sorbitol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Trisodium Ethylenediamine Disuccinate, Water

Other Information

- protect this container from excessive heat and direct sun

Questions or Comments?

Call Toll free 1-855-950-2563

Aloe Up Coco-Mango SPF 50 Broad Spectrum Sunscreen Lotion



BROAD SPECTRUM
SPF 50

4 FL OZ (118 mL)

Drug Facts

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 - 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 of age: Ask a doctor

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Aluminum Starch Octenylsuccinate, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Ethylhexylglycerin, Fragrance, Isodecyl Neopentanoate, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Trisodium Ethylenediamine Disuccinate, Water

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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



ALOE UP BROAD SPECTRUM SPF 50 SUNSCREEN

octisalate, avobenzone, homosalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0560
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	148.95 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	99.4 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.79 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.65 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
SORBITOL (UNII: 506T60A25R)	
ALLANTOIN (UNII: 344S277G0Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPANEDIOL (UNII: 5965N8W85T)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
FRAGRANCE 13576 (UNII: 5EM498GW35)	

Product Characteristics

Color	white (Off white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0560-3	118 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2022	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	M020	06/01/2022	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0560) , manufacture(58443-0560) , label(58443-0560) , analysis(58443-0560)

Revised: 8/2022

Prime Enterprises Inc.