

**ALOE UP BROAD SPECTRUM SPF 30 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 SPORT PERFORMANCE SUNSCREEN LOTION Broad Spectrum SPF 30

Active Ingredients

Avobenzone 3.0%

Octocrylene 3.5%

Homosalate 10%

Octisalate 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

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 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, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Ethylhexylglycerin, 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 in this container from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-800-950-2563

**ALOE UP SPORT PERFORMANCE SUNSCREEN LOTION Broad spectrum SPF 30
- 177 mL**



ALOE UP[®]
SPORT
PERFORMANCE
SUNSCREEN
LOTION

30

**UVA/UVB
BROAD SPECTRUM
SPF 30**



**WATER RESISTANT
(80 MINUTES)**

6 FL OZ (177 mL)

Every Aloe Up product is rooted with a foundation of pure Aloe Vera Gel to ensure a lightweight, non-greasy application. All Aloe Up products are developed with natural elements to provide the cleanest, most comfortable formulas for your skin.

Drug Facts

Active Ingredients	Purpose
Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 3.5%	Sunscreen

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FRAGRANCE FREE / PARABEN FREE / OCTINOXATE FREE
 PHTHALATE FREE / RETINYL PALMITATE FREE



WWW.ALOEUP.COM
 1-800-950-2563

Complies with AS/NZS 2604:2012



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ALOE UP BROAD SPECTRUM SPF 30 SUNSCREEN

octisalate, avobenzone, homosalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0419
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	35.175 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.15 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50.25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
SORBITOL (UNII: 506T60A25R)	
PROPANEDIOL (UNII: 5965N8W85T)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
ALLANTOIN (UNII: 344S277G0Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

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:58443-0419-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part352	03/10/2020	
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Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0419) , manufacture(58443-0419) , label(58443-0419) , analysis(58443-0419)

Revised: 9/2021

Prime Enterprises Inc.