

**ALOE UP BROAD SPECTRUM SPF 30 SUNSCREEN- octisalate, avobenzone, homosalate, octocrylene spray**

**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.*

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**ALOE UP SPORT PERFORMANCE SUNSCREEN Spectrum SPF 30**

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

**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. Keep away from face to avoid breathing it.

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.

**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.

**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

**Active Ingredients**

Avobenzone 3.0%

Octocrylene 3.5%

Homosalate 10.0%

Octisalate 5.0%

***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

***Other Information***

- protect this product from excessive heat and direct sun

***Questions or Comments?***

Call Toll free 1-855-950-2563

**ALOE UP SPORT PERFORMANCE SUNSCREEN Broad spectrum SPF 30**



**ALOE UP<sup>®</sup>**  
**SPORT**  
PERFORMANCE  
SUNSCREEN

**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. Since Aloe Vera Gel and your skin share a similar pH, our formulas absorb quickly without clogging pores. All Aloe Up products are developed with natural elements to provide the cleanest, most comfortable formulas for your skin.

Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Avobenzone 3.0% Homosalate 10.0% Octisalate 5.0% Octocrylene 3.5%	Sunscreen
<b>Uses</b>	
<ul style="list-style-type: none"> <li>helps prevent sunburn</li> <li>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</li> </ul>	
<b>Warnings</b>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>apply liberally 15 minutes before sun exposure</li> <li>reapply:               <ul style="list-style-type: none"> <li>after 80 minutes of swimming or sweating</li> <li>immediately after towel drying</li> <li>at least every 2 hours</li> </ul> </li> <li><b>Sun Protection Measures.</b> 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:               <ul style="list-style-type: none"> <li>limit time in the sun, especially from 10 a.m. – 2 p.m.</li> <li>wear long-sleeve shirts, pants, hats, and sunglasses</li> <li>children under 6 months of age. Ask a doctor</li> </ul> </li> </ul>	
<b>Inactive Ingredients</b>	
Acrylates/C10-30 Alkyl Acrylate Copolymer, Allantoin, Aloe Barbadensis Leaf Juice, Aluminum Starch Octenylsuccinate, Butylphenylmethacrylate, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Ethylhexylglycerin, Isododecane, Isopropyl Alcohol, Isopropyl Myristate, PEG-8, Phenylethyl Alcohol, Polyethylene, Polysorbate 20, Propylparaben, Sodium Hydroxide, Sorbitol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethylamine Ethyleneimine Disuccinate, Water	
<b>Other Information</b>	
protect this product in this container from excessive heat and direct sun.	
<b>Questions or Comments?</b>	
Call toll free 1-800-950-2563	

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



WWW.ALOEUP.COM

1-800-950-2563

Complies with AQ/MS 2604.2012



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## ALOE UP BROAD SPECTRUM SPF 30 SUNSCREEN

octisalate, avobenzone, homosalate, octocrylene spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0326
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL

<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	35 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
SORBITOL (UNII: 506T60A25R)	
PROPANEDIOL (UNII: 5965N8W85T)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
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)	
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

### Product Characteristics

<b>Color</b>	white (Off white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0326-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/03/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/03/2018	

**Labeler** - Prime Enterprises Inc. (101946028)

**Registrant** - Prime Enterprises Inc. (101946028)

**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0326) , manufacture(58443-0326) , label(58443-0326) , analysis(58443-0326)

Revised: 5/2020

Prime Enterprises Inc.