

**ALOE UP BROAD SPECTRUM SPF 50 SUNSCREEN- homosalate, octisalate, avobenzone, octocrylene spray  
Prime Packaging 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 Broad Spectrum SPF 50 Kids  
Continuous Spray**

**INACTIVE INGREDIENTS**

Aloe Barbadosensis Leaf Extract, Cocos Nucifera (Coconut) Oil, Diethylhexyl 2,6-Naphthalate, Mineral Oil, Polyester-8, SD Alcohol 40-B, VA/Butyl Maleate/Isobornyl Acrylate Copolymer

**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. Contents under pressure - do not puncture or incinerate. Do not store at temperatures above 120 F.

**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.

**Flammable:** Do not use near heat, flame or while smoking

**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%

Homosalate 15%

Octisalate 5%

Octocrylene 2.75%

### ***Directions***

- Spray liberally and spread evenly 15 minutes before sun exposure
- Hold container 4 to 6 inches from the skin to apply
- Do not spray directly into face. Spray on hands then apply to face.
- Do not apply in windy conditions
- Use in well-ventilated area
- 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 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

### ***Other Information***

- Protect this product from excessive heat and direct sun
- Avoid spraying on fabrics - could cause discoloration
- Store at 20° to 25°C (68° to 77°F)

### ***Questions or Comments?***

Call toll free 1-800-950-2563 or visit [www.aloeup.com](http://www.aloeup.com)

**ALOE UP SPORT PERFORMANCE SUNSCREEN Broad spectrum SPF 50 Kids - 5.5 oz (156 g)**



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

**50**

**UVA/UVB  
BROAD SPECTRUM  
SPF 50 CONTINUOUS SPRAY**



**WATER RESISTANT  
(80 MINUTES)**

Net Wt. 5.5 oz. (156 g)



**Drug Facts**

**Active Ingredients**

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Homosalate 15%  
Octisalate 5%  
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When using this product keep out of eyes. Rinse with water to remove. Keep away from face to avoid breathing it. Contents under pressure - do not puncture or incinerate. Do not store at temperatures above 120°F.

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.

Flammable: Do not use near heat, flame or while smoking

**Directions**

• Spray liberally and spread evenly by hand 15 minutes before sun exposure

• Hold container 4 to 6 inches from the skin to apply

• Do not spray directly into face. Spray on hands then apply to face.

• Do not apply in windy conditions

• Use in a well-ventilated area

• 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 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

**Inactive Ingredients**

Aloe Barbadosensis Leaf Extract, Cocos Nucifera (Coconut) Oil, Diethylhexyl 2,6-Naphthalate, Mineral Oil (Paraffinum Liquidum), Polyester-8, SD Alcohol 40-B (Alcohol Denat.), VA/Butyl Maleate/Isobornyl Acrylate Copolymer

**Other Information**

• Protect this product from excessive heat and direct sun

• Avoid spraying on fabrics - could cause discoloration

• Store at 20° to 25°C (68° to 77°F)

**Questions or Comments?**

Call to I free 1-800-950-2563 or visit [www.aloeup.com](http://www.aloeup.com)

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Manufactured for: ALOE UP 9700 W. 78th St., Ste 112,  
Eden Prairie, Minnesota 55344



Complies with AS/NZS 2604:2012

**ALOE UP BROAD SPECTRUM SPF 50 SUNSCREEN**

homosalate, octisalate, avobenzone, octocrylene spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13630-0183
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.5 mg in 1 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

**HOMOSALATE** (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 150 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>DIETHYLHEXYL 2,6-NAPHTHALATE</b> (UNII: I0DQJ7YGXM)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED)</b> (UNII: T9296U138P)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	

### Product Characteristics

<b>Color</b>	yellow (Light Yellow)	<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:13630-0183-4	156 g in 1 CANISTER; Type 0: Not a Combination Product	08/28/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/28/2016	

**Labeler** - Prime Packaging Inc. (805987059)

**Registrant** - Prime Packaging Inc. (805987059)

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	manufacture(13630-0183) , label(13630-0183) , pack(13630-0183) , analysis(13630-0183)

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	label(13630-0183) , pack(13630-0183)