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.

ALOE UP SPORT PERFORMANCE SUNSCREEN Broad Spectrum SPF 50 Continuous Spray

INACTIVE INGREDIENTS

Aloe Barbadensis 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%

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 protecion 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

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







Active Ingredients

Avobenzone 3% Homosalate 15% Octisalate 5% Octocrylene 2.75% Purpose

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. 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 Barbadensis Leaf Extract, Cocos Nucifera (Coconut) Oil, Diethyhexyl 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 toll free 1-800-950-2563 or visit www.aloeup.com







Net Wt. 5.5 oz. (156 g)

WATER RESISTANT (80 MINUTES)

PERFORMANCE

SUNSCREEN

UVA/UVB

BROAD SPECTRUM

SPF 50 CONTINUOUS SPRAY

ALOE UP BROAD SPECTRUM SPF 50 SUNSCREEN

homosalate, octisalate, avobenzone, octocrylene spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:13630-0181

Route of Administration TOPICAL

Active Ingredient/Active Moiety Basis of Strength Strength **Ingredient Name** OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) 27.5 mg in 1 g **OCTOCRYLENE AVOBENZONE** (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) **AVOBENZONE** 30 mg in 1 g OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) **OCTISALATE** 50 mg in 1 g **HOMOSALATE** (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S) **HOMOSALATE** 150 mg in 1 g

Manufactured for ALCO EV 9700 W. 76th St., Ste 112,

Inactive Ingredients	
Ingredient Name	Strength
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: IODQJ7YGXM)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
ALCOHOL (UNII: 3K9958V90M)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Product Characteristics			
Color	yellow (Light Yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:13630- 0181-4	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)

EstablishmentNameAddressID/FEIBusiness OperationsPrime Enterprises
Inc.101946028manufacture(13630-0181) , label(13630-0181) , pack(13630-0181) , analysis(13630-0181)

Establishment				
Name	Address	ID/FEI	Business Operations	
Prime Packaging Inc.		805987059	pack(13630-0181) , label(13630-0181)	

Revised: 10/2021 Prime Packaging Inc.