

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 Kids Continuous Spray

Active Ingredients

Avobenzone 3%

Homosalate 15%

Octisalate 5%

Octocrylene 2.75%

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. 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 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

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

Other Information

- protect this product from excessive heat and direct sun
- avoid spraying on fabrics - could cause discoloration.

Questions or Comments?

Call toll free 1-800-950-2563 or visit www.aloeup.com

Aloe Up Sport Performance Broad spectrum SPF 50 Kids - 5.5 oz (156 g)



ALOE UP[®]
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	}	Purpose
Avobenzone 3%		Sunscreen
Homosalate 15%		
Octisalate 5%		
Octocrylene 2.75%		

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 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



Complies with AS/NZS 2604:2012

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

ALOE UP BROAD SPECTRUM SPF 50 SUNSCREEN

homosalate, octisalate, avobenzone, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0208
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	23.35 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.47 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	42.45 mg in 1 mL

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) HOMOSALATE 127.35 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0208-4	184 mL in 1 CANISTER; Type 0: Not a Combination Product	11/10/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/10/2016	

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	manufacture(13630-0208) , label(13630-0208) , pack(13630-0208) , analysis(13630-0208)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	label(13630-0208) , pack(13630-0208)