

ALOE UP BROAD SPECTRUM SPF 30- avobenzone, homosalate, octisalate and 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 BROAD SPECTRUM SPF 50

Aloe Up Lil' Kids SPF 50 Continuous Spray Sunscreen

Aloe Up Pro Broad Spectrum SPF 30 Continuous Spray Sunscreen provides sun protection at the touch of a button. Our unique formula allows quick and easy application; no pumping or squeezing required. Lightweight formula sprays at any angle and applies clear.

Drug Facts	
Active Ingredients Avobenzone 3% Homosalate 10% 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 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 Barbadosis 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.	
Questions or Comments? Call toll free 1-800-950-2583	

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 www.aloeup.com 9700 W 76th St. Ste. 112
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 Made in USA

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Octisalate 5%
Octocrylene 2.75%
Sunscreen

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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 - not puncture or incinerate. Do not store at temperatures above 120°F

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0095
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	24.9 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	83 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	41.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	22.8 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
MINERAL OIL (UNII: T5L8T28FGP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0095-4	177 mL in 1 CAN; Type 0: Not a Combination Product	07/27/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/27/2015	

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		805987059	pack(13630-0095) , manufacture(13630-0095) , label(13630-0095)

Revised: 9/2015

Prime Packaging Inc.