

ALOE UP KIDS BROAD SPECTRUM SPF 50 SUNSCREEN- octisalate, avobenzone, homosalate, octocrylene, octinoxate gel
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.

ALOE UP KIDS SPORT PERFORMANCE SUNSCREEN Spectrum SPF 50

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.

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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 10%

Homosalate 5.0%

Octisalate 5.0%

Octinoxate 6.0%

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 KIDS SPORT PERFORMANCE SUNSCREEN Broad spectrum SPF 50



ALOE UP
KIDS
SPORT
SUNSCREEN

50

UVA/UVB
BROAD SPECTRUM
SPF 50



WATER RESISTANT
(80 MINUTES)

6 FL OZ (177 mL)

Aloe Up Kids is built for even the most sensitive skin. A foundation of pure Aloe Vera Gel ensures a lightweight, non-greasy application. Since Aloe Vera Gel and your skin share a similar pH, our formulas absorb quickly and do not run in eyes or sting. All Aloe Up products are developed with natural elements to provide the cleanest, most comfortable sunscreen for your skin.

Drug Facts

Active Ingredients	Purpose
Avobenzone 3.0% Homosalate 5.0% Octinoxate 6.0% Octisalate 5.0% Octocrylene 10%	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.

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.

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 10 a.m. – 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months of age: Ask a doctor

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Aluminum Starch Octenylsuccinate, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis 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

Other Information

- protect this container from excessive heat and direct sun.

Questions or Comments?
Call toll free 1-800-950-2563

FRAGRANCE FREE / PARABEN FREE
PHTHALATE FREE / RETINYL PALMITATE FREE



WWW.ALOEUP.COM

1-800-950-2563

Complies with AS/NZS 2604:2012



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ALOE UP KIDS BROAD SPECTRUM SPF 50 SUNSCREEN

octisalate, avobenzone, homosalate, octocrylene, octinoxate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 443-030 1
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	49.7 mg in 1 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	99.4 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.82 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.7 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	59.64 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 HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)	
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: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
N-BUTYLPHthalimide (UNII: 5TH1DKT35E)	
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)	

Product Characteristics

Color	white (Off white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0301-4	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(58443-0301) , manufacture(58443-0301) , label(58443-0301) , analysis(58443-0301)

Revised: 5/2020

Prime Enterprises Inc.