

**ALOE SUNSCREEN- homosalate, octisalate, avobenzone, ensulizole and octocrylene lotion
Aloe Vera of America, 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.

Active Ingredients Purpose

Avobenzone 2.5%

Ensulizole 3.0%

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 2.79% 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 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 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 juice (stabilized* aloe vera gel), butyloctyl salicylate, caprylic/capric triglyceride, cetearyl olivate, ceteth-20, cetyl alcohol, cetyl dimethicone, cetyl PEG/PPG-10/1 dimethicone, fragrance (parfum), glycerin, glyceryl stearate, hexyl laurate, methylisothiazolinone, PEG-75 stearate, phenoxyethanol, polyglyceryl-4 isostearate, sodium chloride, sorbitan olivate, steareth-20, tocopheryl acetate, triethanolamine, water (aqua), xanthan gum

Other information

- protect this product from excessive heat and direct sun
- tube sealed for your protection

Questions: Call 1-888-440-2563, Monday - Friday, 9:00 a.m. to 4:00 p.m. PT.



ALOE SUNSCREEN



**WATER RESISTANT
(80 MINUTES)**

4 FL. OZ. (118 mL)
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Drug Facts

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Sunscreen

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*U.S. Patent Nos. 6713095 & 6869624.

Exclusively distributed by:

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Scottsdale, Arizona 85258 USA

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Made in USA



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K41US

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ALOE SUNSCREEN

homosalate, octisalate, avobenzone, ensulizole and octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11697-199
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10.0 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.5 g in 100 mL
ENSULIZOLE (UNII: 9YQ9D11W42) (ENSULIZOLE - UNII:9YQ9D11W42)	ENSULIZOLE	3.0 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.79 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	29.4 g in 100 mL
WATER (UNII: 059QF0KO0R)	29.2 g in 100 mL
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	3.0 g in 100 mL
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	3.0 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	2.0 g in 100 mL
CETEARYL OLIVATE (UNII: 58B69Q84JO)	1.7 g in 100 mL
SORBITAN OLIVATE (UNII: MDL271E3GR)	1.4 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	1.0 g in 100 mL
CETYL ALCOHOL (UNII: 936JST6JCN)	0.7 g in 100 mL
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	0.7 g in 100 mL
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	0.7 g in 100 mL
HEXYL LAURATE (UNII: 4CG9F9W01Q)	0.7 g in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.3 g in 100 mL
PEG-75 STEARATE (UNII: OT38R0N74H)	0.3 g in 100 mL
TRIETHYLAMINE (UNII: VOU728O6AY)	0.3 g in 100 mL
XANTHAN GUM (UNII: TTV12P4NEE)	0.2 g in 100 mL
CETETH-20 (UNII: I835H2IHHX)	0.2 g in 100 mL
STEARETH-20 (UNII: L0Q8IK9E08)	0.1 g in 100 mL
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.1 g in 100 mL
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	0.01 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11697-199-05	118.000 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/06/2011	

Labeler - Aloe Vera of America, Inc. (049049463)

Registrant - Aloe Vera of America, Inc. (049049463)

Establishment

Name	Address	ID/FEI	Business Operations
Aloe Vera of America, Inc.		049049463	manufacture(11697-199)

Revised: 1/2015

Aloe Vera of America, Inc.