

**ALOE SUNSCREEN- homosalate, octisalate, avobenzone, ensulizole and octocrylene spray
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 2.7%

Ensulizole 4.0%

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. Keep away from face to avoid breathing product.

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

Shake well before use.

- hold container 4 to 6 inches from the skin and spray generously and spread evenly by hand 15 minutes before sun exposure
- do not spray directly into face. Spray on hands then apply to face.
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- do not apply in windy conditions
- use in well-ventilated area
- **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

acrylates/C12-22 alkyl methacrylate copolymer, acrylates copolymer, aloe barbadensis leaf juice (stabilized* aloe vera gel), butyloctyl salicylate, cetareth-25, diethylhexyl carbonate, disodium

ethylene dicocamide PEG-15 disulfate, disodium EDTA, fragrance (parfum), methylisothiazolinone, neopentyl glycol diheptanoate, panthenol, pentylene glycol, phenoxyethanol, polyester-7, propanediol, styrene/acrylates copolymer, tocopheryl acetate, triethanolamine, water (aqua)

Other information

- protect this product from excessive heat and direct sun

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

Drug Facts

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|--|-----------|
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SKU 319

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ALOE SUNSCREEN

homosalate, octisalate, avobenzone, ensulizole and octocrylene spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11697-319 |
| 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: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE | 5.0 g in 100 mL |
| ENSULIZOLE (UNII: 9 YQ9 D11W42) (ENSULIZOLE - UNII:9 YQ9 D11W42) | ENSULIZOLE | 4.0 g in 100 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 3.0 g in 100 mL |
| OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM) | OCTOCRYLENE | 2.79 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|------------------|
| ALOE VERA LEAF (UNII: ZY8 1Z83H0 X) | 29.3 g in 100 mL |
| WATER (UNII: 059QF0KO0R) | 27.3 g in 100 mL |
| PROPANEDIOL (UNII: 5965N8W85T) | 3.0 g in 100 mL |
| DIETHYLHEXYL CARBONATE (UNII: YCD50O0Z6L) | 3.0 g in 100 mL |
| BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3) | 3.0 g in 100 mL |
| POLYESTER-7 (UNII: 0841698D2F) | 2.4 g in 100 mL |
| STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A) | 1.9 g in 100 mL |
| NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X) | 1.6 g in 100 mL |
| CETEARETH-25 (UNII: 8FA93U5T67) | 0.7 g in 100 mL |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | 0.3 g in 100 mL |
| DISODIUM ETHYLENE DICAMIDE PEG-15 DISULFATE (UNII: QI9A6U005W) | 0.3 g in 100 mL |
| PENTYLENE GLYCOL (UNII: 50C1307PZG) | 0.1 g in 100 mL |
| PANTHENOL (UNII: WV9CM0O67Z) | 0.1 g in 100 mL |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | 0.01 g in 100 mL |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | 0.01 g in 100 mL |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | 0.1 g in 100 mL |
| TROLAMINE (UNII: 9O3K93S3TK) | 0.3 g in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------|----------------------|--------------------|
| 1 | NDC:11697-319-07 | 178.000 mL in 1 BOTTLE, SPRAY | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 08/16/2010 | |

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(11697-319) |