

ALOE UP SPF 30 C/S SUNSCREEN WITH ALOE VERA- 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 SPF 30 C/S Sunscreen Aloe Vera

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 Barbadensis Extract, Cocos Nucifera (Coconut) Oil, Diethylhexyl 2,6-Naphthalate, Fragrance (Parfum), 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°C to 25°C (68°F to 77°F)

Questions or comments?

Call toll free 1-800-950-2563

SPF 30 C/S Sunscreen Aloe Vera



COCO-MANGO
SUNSCREEN
MIST

ALOE UP[®]

30

ALOE ENRICHED

OXYBENZONE &
OCTINOXATE FREE

PARABEN FREE

WATER RESISTANT
(80 MINUTES)

REEF SAFE

BROAD SPECTRUM
SPF 30

Net Wt. 5.5 oz. (156 g)



Drug Facts

| Active Ingredients | Purpose |
|---|-----------|
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WWW.ALOEUP.COM
1-800-950-2563



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ALOE UP SPF 30 C/S SUNSCREEN WITH ALOE VERA

avobenzone, homosalate, octisalate, and octocrylene spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13630-0224 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|---|-------------|------------------|
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 83.9 mg in 1 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 41.95 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 23.07 mg in 1 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 25.17 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| COCONUT OIL (UNII: Q9L0O73W7L) | |
| DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P) | |
| ALCOHOL (UNII: 3K9958V90M) | |

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:13630-0224-4 | 185 mL in 1 CAN; Type 0: Not a Combination Product | 05/20/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 05/20/2019 | |

Labeler - Prime Packaging Inc (805987059)

Registrant - Prime Packaging Inc (805987059)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|--|
| Prime Enterprises Inc | | 101946028 | manufacture(13630-0224) , analysis(13630-0224) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|--------------------------------------|
| Prime Packaging Inc | | 805987059 | label(13630-0224) , pack(13630-0224) |

