

ULTA BEAUTY SPF 50 BROAD SPECTRUM SUNSCREEN- avobenzene, homosalate, octisalate, octocrylene and, oxybenzone 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.

Ultra Beauty SPF 50 Broad Spectrum Sunscreen

Active Ingredients

Avobenzene 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

Oxybenzone 2%

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 and 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

Acrylates/Dimethicone Copolymer, Aloe Barbadensis Leaf Juice, Camellia Oleifera (Green Tea) Leaf Extract, Cyclopentasiloxane, Diethylhexyl 2,6-Naphthalate, Fragrance, Glycerin, Polyester-8, SD Alcohol 40-B, Tocopheryl Acetate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Water

Other Information

- protect this product from excessive heat and direct sun
- avoid spraying on fabrics - could cause discoloration

Question or comments?

Call 1-866-983-8582

Ulta Beauty SPF 50 Broad Spectrum Sunscreen

**BROAD SPECTRUM
SPF 50 SUNSCREEN**

- Aloe Vera, Green Tea and Vitamin E help soothe and hydrate skin

| | |
|---|---------------------------------|
| Drug Facts | |
| Active ingredients Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 2.75% Oxybenzone 4% | 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 Acrylates/Dimethicone Copolymer, Aloe Barbadensis Leaf Juice, Camellia Oleifera (Green Tea) Leaf Extract, Cyclopentasiloxane, Diethylhexyl 2,6-Naphthalate, Fragrance, Glycerin, Polyester-8, SD Alcohol 40-B, Tocopheryl Acetate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Water | |
| Other information • protect this product from excessive heat and direct sun • avoid spraying on fabrics - could cause discoloration | |
| Questions or comments? Call 1-866-983-8582 | |

FREE OF OIL, PARABENS & SULFATES

MADE IN USA
FROM US AND IMPORTED INGREDIENTS
DISTRIBUTED BY ULTA INC.
BOLINGBROOK, IL 60440
ULTA.COM



ULTA beauty™

50
Sun Protection
**BROAD
SPECTRUM
SPF 50
SUNSCREEN**

Mist

Water-Resistant
(80 minutes)

Oil-Free

UVA/UVB Protection

6 fl. oz. / 177 mL

ULTA BEAUTY SPF 50 BROAD SPECTRUM SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene and, oxybenzone spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13630-0120 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 25.5 mg in 1 mL |
| OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE | 42.5 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM) | OCTOCRYLENE | 23.34 mg in 1 mL |
| OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y) | OXYBENZONE | 34 mg in 1 mL |

| | | |
|--|------------|---------------|
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 85 mg in 1 mL |
|--|------------|---------------|

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| DIBUTYL MALEATE (UNII: 4X371TMK9K) | |
| WATER (UNII: 059QF0K00R) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CYCLOMETHICONE 5 (UNII: 0TH5PC10R) | |
| DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6) | |

Product Characteristics

| | | | |
|----------|--------|--------------|--|
| Color | yellow | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13630-0120-4 | 177 mL in 1 CAN; Type 0: Not a Combination Product | 12/30/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 12/30/2016 | |

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|--|
| Prime Enterprises Inc | | 101946028 | manufacture(13630-0120) , analysis(13630-0120) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|--------------------------------------|
| Prime Packaging Inc. | | 805987059 | pack(13630-0120) , label(13630-0120) |

