

**ULTA BEAUTY BROAD SPECTRUM SPF 30 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion**  
**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.*

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**Ulta Beauty SPF 30 Broad Spectrum Sunscreen**

***Active Ingredients***

Avobenzone 3%

Homosalate 7.5%

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.

**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 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/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Oleifera (Green Tea) Leaf Extract, Caprylyl Glycol, Carbomer, Cucumis Sativus (Cucumber) Extract, Disodium EDTA, Fragrance, Glycerin, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Phenoxyethanol, Polyethylene, Polysorbate 20, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

### Other Information

- protect this product from excessive heat and direct sun
- avoid contact with fabrics - could cause discoloration

### Question or comments?

Call 1-866-697-9868

## Ulta Beauty SPF 30 Broad Spectrum Sunscreen

|   |                |
|---|----------------|
| <b>Drug Facts</b>   |                |
| <b>Active ingredients</b>   | <b>Purpose</b> |
| Avobenzone 3%<br>Homosalate 7.5%<br>Octisalate 5%<br>Octocrylene 2.75%<br>Oxybenzone 2%   | Sunscreen      |
| <b>Uses</b>   |                |
| <ul style="list-style-type: none"> <li>• helps prevent sunburn</li> <li>• if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun</li> </ul>   |                |
| <b>Warnings</b>   |                |
| 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.   |                |
| <b>Directions</b>   |                |
| <ul style="list-style-type: none"> <li>• apply liberally 15 minutes before sun exposure</li> <li>• reapply: <ul style="list-style-type: none"> <li>• after 80 minutes of swimming or sweating</li> <li>• immediately after towel drying</li> <li>• at least every 2 hours</li> </ul> </li> <li>• <b>Sun Protection Measures.</b> 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: <ul style="list-style-type: none"> <li>• limit time in the sun, especially from 10 a.m. - 2 p.m.</li> <li>• wear long-sleeve shirts, pants, hats, and sunglasses</li> <li>• children under 6 months: Ask a doctor</li> </ul> </li> </ul> |                |
| <b>Inactive ingredients</b>   |                |
| Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Oleifera (Green Tea) Leaf Extract, Caprylyl Glycol, Carbomer, Cucumis Sativus (Cucumber) Extract, Disodium EDTA, Fragrance, Glycerin, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Phenoxyethanol, Polyethylene, Polysorbate 20, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water   |                |
| <b>Other information</b>  |                |
| <ul style="list-style-type: none"> <li>• protect this product from excessive heat and direct sun</li> <li>• avoid contact with fabrics - could cause discoloration</li> </ul>   |                |
| <b>Questions or comments?</b>   |                |
| Call 1-866-697-9868   |                |
| <p>FREE OF OIL, PARABENS &amp; SULFATES<br/>MADE IN USA FROM US AND IMPORTED INGREDIENTS<br/>DISTRIBUTED BY ULTA INC. BOLINGBROOK, IL 60440 ULTA.COM</p>  |                |
|    |                |

ULTA beauty™

# 30

Sun Protection  
BROAD  
SPECTRUM  
SPF 30  
SUNSCREEN

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Lotion

Water-Resistant  
(80 minutes)

Oil-Free

UVA/UVB Protection

6 fl. oz. / 177 mL

**ULTA BEAUTY BROAD SPECTRUM SPF 30 SUNSCREEN**

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:58443-0244 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength         |
|--|-------------------|------------------|
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE        | 50.5 mg in 1 mL  |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)   | OXYBENZONE        | 20.2 mg in 1 mL  |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 27.78 mg in 1 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE        | 30.3 mg in 1 mL  |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE        | 75.75 mg in 1 mL |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X)  |          |
| CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)  |          |
| N-BUTYLPHthalimide (UNII: 5TH1DKT35E)  |          |
| ISOPROPYLPHthalimide (UNII: 1J1MM83329)  |          |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)                                       |          |
| CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)  |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)   |          |
| COCOA BUTTER (UNII: 512OYT1CRR)  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                                    |          |
| SORBITAN MONOLEATE (UNII: 06XEA2VD56)  |          |
| EDETATE DISODIUM (UNII: 7FLD91C86K)  |          |
| GLYCERIN (UNII: PDC6A3C0OX)  |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                                     |          |
| CUCUMBER (UNII: YY7C30VXJT)  |          |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0)  |          |
| HYPROMELLOSES (UNII: 3NXW29V3WO)   |          |
| POLYSORBATE 20 (UNII: 7T1F30V5YH)  |          |
| SODIUM HYDROXIDE (UNII: 55X04QC32I)  |          |
| WATER (UNII: 059QF0KO0R)   |          |

### Product Characteristics

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    | white | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   |       | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

### Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:58443-0244-4 | 177 mL in 1 TUBE; Type 0: Not a Combination Product | 12/27/2016           |                    |

  

| Marketing Information |  |                      |                    |  |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph final   | part352                                  | 12/27/2016           |                    |  |

**Labeler** - Prime Enterprises Inc. (101946028)

**Registrant** - Prime Enterprises Inc. (101946028)

**Establishment**

| Name                   | Address | ID/FEI    | Business Operations   |
|------------------------|---------|-----------|---|
| Prime Enterprises Inc. |         | 101946028 | pack(58443-0244) , manufacture(58443-0244) , label(58443-0244) , analysis(58443-0244) |

Revised: 1/2020

Prime Enterprises Inc.