ULTA BEAUTY BROAD SPECTRUM SPF 30 TINTED MINERAL SUNSCREEN- titanium dioxide, zinc oxide 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.

Ulta Beauty SPF 30 Broad Spectrum Tinted Mineral Sunscreen

Active Ingredients

TItanium Dioxide 3%

Zinc Oxide 3%

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

Allantoin, Alumina, Butyrospermum Parkii (Shea) Butter, Camellia Oleifera (Green Tea) Leaf Extract, Cetyl PEG/PPG-10/1 Dimethicone, Cucumis Sativus (Cucumber) Extract, Cyclopentasiloxane, Dimethicone Crosspolymer, Disteardimonium Hectorite, Ethylhexylglycerin, Fragrance, Glycerin,

Hexyl Laurate, Iron Oxides, Linum Usitatissimum (Linseed) Seed Oil, Oenothera Biennis (Evening Primrose) Oil, PEG-10 Dimethicone, Phenoxyethanol, Plankton Extract, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Rosa Canina Fruit Oil, Silica, Stearic Acid, Tocopheryl Acetate, Triethoxycaprylylsilane, Water

Other Information

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

Question or comments?

Call 1-866-983-8582

Ulta Beauty SPF 30 Broad Spectrum Tinted Face Mineral Sunscreen



Drug Facts

Active ingredients

Titanium Dioxide 3% Zinc Oxide 3%

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

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Inactive ingredients: Allantoin, Alumina, Butyrospermum Parkii (Shea) Butter, Camellia Oleifera (Green Tea) Leaf Extract, Cetyl PEG/PPG-10/1 Dimethicone, Cucumis Sativus (Cucumber) Extract, Cyclopentasiloxane, Dimethicone Crosspolymer, Disteardimonium Hectorite, Ethylhexylglycerin, Fragrance, Glycerin, Hexyl Laurate, Iron Oxides, Linum Usitatissimum (Linseed) Seed Oil, Oenothera Biennis (Evening Primrose) Oil, PEG-10 Dimethicone, Phenoxyethanol, Plankton Extract, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Rosa Canina Seed Oil, Silica, Stearic Acid, Tocopheryl Acetate, Triethoxycaprylylsilane, Water

Other information:

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

Questions or comments? Call 1-866-983-8582

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ULTA BEAUTY BROAD SPECTRUM SPF 30 TINTED MINERAL SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source)

Route of Administration TOPICAL

NDC:58443-0245

| Active Ingredient/Active Moiety | | | |
|--|-------------------|------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP) | TITANIUM DIO XIDE | 31.38 mg in 1 mL | |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 31.38 mg in 1 mL | |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ) | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | |
| EVENING PRIMRO SE O IL (UNII: 3Q9L08K71N) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) | |
| HEXYL LAURATE (UNII: 4CG9F9W01Q) | |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8 PR7V1SVM0) | |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820 DPX33S7) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| ALUMINUM O XIDE (UNII: LMI26 O 69 33) | |
| .ALPHATO COPHEROL ACETATE (UNII: 9E8 X80 D2L0) | |
| ALLANTO IN (UNII: 344S277G0Z) | |
| SHEA BUTTER (UNII: K49155WL9Y) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X) | |
| CUCUMBER (UNII: YY7C30 VXJT) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6) | |
| DISTEARDIMO NIUM HECTORITE (UNII: X687XDK09L) | |
| FERRIC O XIDE RED (UNII: 1K09F3G675) | |
| WATER (UNII: 059QF0KO0R) | |
| LINSEED OIL (UNII: 84XB4DV00W) | |
| TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570 VEV8 XK) | |

| Product Characteristics | | | |
|-------------------------|-------|--------------|--|
| Color | brown | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| Packaging | | | | |
|-----------|--------------------|--|-----------------------------|---------------------------|
| ı | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| ı | 1 NDC:58443-0245-3 | 59 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(58443-0245), manufacture(58443-0245), label(58443-0245), analysis(58443-0245) |

Revised: 1/2020 Prime Enterprises Inc.