# SPECTER CAPITAL TROPICAL BLEND BROAD SPECTRUM SPF 30 SUNSCREENavobenzone, homosalate, octisalate, octocrylene, 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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# Specter Capital Tropical Blend Broad Spectrum SPF 30 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 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/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Methylisothiazolinone, Methylparaben, Polyethylene, Polysorbate 20, Propylene Glycol, Propylparaben, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethanolamine, Water

# Other Information

- protect this product from excessive heat and direct sun
- stored at controlled room temperature

## Specter Capital Tropical Blend Broad Spectrum SPF 30 Sunscreen





# SPECTER CAPITAL TROPICAL BLEND BROAD SPECTRUM SPF 30 SUNSCREEN avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:58443-0236 Route of Administration TOPICAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)   | OXYBENZONE  | 19.8 mg in 1 mL |
|--|-------------|-----------------|
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE  | 74.3 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 27.3 mg in 1 mL |
| OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) | OCTISALATE  | 49.6 mg in 1 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE  | 29.7 mg in 1 mL |

| Inactive Ingredients   |          |
|--|----------|
| Ingredient Name  | Strength |
| N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)  |          |
| ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)  |          |
| POLYSORBATE 20 (UNII: 7T1F30V5YH)  |          |
| COCOA BUTTER (UNII: 512OYT1CRR)  |          |
| EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)  |          |
| TROLAMINE (UNII: 903K93S3TK)   |          |
| METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)                                       |          |
| METHYLPARABEN (UNII: A2I8C7HI9T)   |          |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)   |          |
| HYPROMELLOSES (UNII: 3NXW29 V3WO)  |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)  |          |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)   |          |
| CARBOMER 940 (UNII: 4Q93RCW27E)  |          |
| CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L) |          |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                                      |          |
| ALKYL (C12-15) BENZO ATE (UNII: A9EJ3J61HQ)                                      |          |
| WATER (UNII: 059QF0KO0R)   |          |
| SORBITAN MONOOLEATE (UNII: 06 XEA2VD56)  |          |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)                                     |          |

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

| Packaging          |   |                             |                           |  |
|--------------------|---|-----------------------------|---------------------------|--|
| # Item Code        | Package Description                                 | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |  |
| 1 NDC:58443-0236-9 | 3785 mL in 1 JUG; Type 0: Not a Combination Product | 05/31/2016                  |                           |  |

| Marketing Information |  |                      |                    |  |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph final   | part352                                  | 05/31/2016           |                    |  |
|                       |  |                      |                    |  |

# Registrant - Prime Enterprises Inc. (101946028)

| Establishment          |         |               |  |
|------------------------|---------|---------------|--|
| Name                   | Address | ID/FEI        | Business Operations  |
| Prime Enterprises Inc. |         | 10 19 46 0 28 | manufacture (58443-0236), label (58443-0236), analysis (58443-0236), pack (58443-0236) |

Revised: 1/2020 Prime Enterprises Inc.