

FT SPF30 SUN STICK- spf30 sun stick - ft stick
Tropical Enterprises International, 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.

FT Broad Spectrum Spf30 Sunstick 275

Avobenzone 2%

Octyl Salate 5%

Homosalate 15%

Octinoxate 7.5%

Uses * Helps prevent sunburn

Warnings

- **For external use only**
- **Do not use** on damaged or broken skin
- **Stop use and ask a doctor** if rash occurs
- **When using this product** keep out of eyes. Rinse with water to remove
- **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

- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months of age: **Ask a doctor**

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 value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10a.m. - 2p.m.
- wear long sleeved shirts, pants, hats and sunglasses

Inactive Ingredients: Parrafin, Ethylhexyl Palmitate, Oxokerite, Ephorbia Cerifera, Cera Alba, Cutyloctyl Sallicylate, Polyethylene, Polyester-8, Cetyl Alcohol, DL-alpha-Tocopheryl acetate, Butylated hydroxytoluene, Ascorbic Acid

Other Information

Protect this product from excessive heat and direct sun.



**Broad Spectrum
SPF 30 Sun Stick**

Net Wt. .6 oz.

Drug Facts

Active Ingredients:

- Avobenzone (2%)
- Homosalate (15%)
- Octinoxate (7.5%)
- Octylsalate (5%)

Purpose
.....Sunscreen

**We got
your back.**

**This
is that
place**



Drug Facts (continued)

Uses • Helps prevent sunburn

Warnings

- **For external use only**
- **Do not use** on damaged or broken skin • **Stop use and ask a doctor** if rash occurs • **When using this product** • keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • Apply liberally 15 minutes before sun exposure

- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months of age: **Ask a doctor**
- **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 value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10a.m. - 2p.m.
 - wear protective clothing, hats and sunglasses.

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FT SPF30 SUN STICK

spf30 sun stick - ft stick

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58418-275 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------|-------------------|----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 7.5 mg in 1 mL |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 15 mg in 1 mL |
| OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE | 5 mg in 1 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 2 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------------------------------------------------------|----------|
| WHITE WAX (UNII: 7G1J5DA97F) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| PARAFFIN (UNII: I9O0E3H2ZE) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3) | |
| POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | |
| CANDELILLA WAX (UNII: WL0328HX19) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| CERESIN (UNII: Q1LS2UJO3A) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:58418-275-05 | 15 mL in 1 CANISTER; Type 0: Not a Combination Product | 08/31/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph not final | part352 | 08/31/2018 | |

Labeler - Tropical Enterprises International, Inc (091986179)

Registrant - Tropical Enterprises International, Inc. (091986179)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------------------|---------|-----------|---------------------|
| Tropical Enterprises International, Inc. | | 091986179 | label(58418-275) |

Revised: 8/2018

Tropical Enterprises International, Inc