

ECO SPF30 SUN STICK- spf30 broad spectrum sun stick 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.

Broad Spectrum Spf30 Sunstick - EL x274

Avobenzone (1%)

Octinoxate (7.5%)

Octisalate (5%)

Oxybenzone (4%)

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.

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.
- reapply:
 - after 40 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-sleeved shirts; pants, hats and sunglasses
 - children under 6 months: Ask a doctor.

Inactive Ingredients

*Aloe Barbadensis (Aloe Vera) Leaf Oil, *Cera Flava (Beeswax), *Calendula Officinalis (Calendula) Flower Extract, *Cocos Nucifera (Cocounut) Oil, *Helianthus Annuus (Sunflower) Seed Oil, *Rosmarinus Officinalis (Rosemary) Leaf Extract, *Theobroma Cacao (Cocoa) Seed Butter, Mixed Tocopherols (Vitamin E).

*Organic Ingredients

Other Information

Protect this product from excessive heat and direct sunlight.

Questions or Comments?

Call 1.866.326.5477

Lxxxxx

Drug Facts (continued)

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safety seal
lines up here

SPF 30 Face Stick

Drug Facts

Active Ingredients:

Avobenzone (1%)
Octinoxate (7.5%)

Purpose:

Sunscreen
Sunscreen

Active Ingredients:

Octisalate (5%)
Oxybenzone (4%)

Purpose:

Sunscreen
Sunscreen

Net Wt. .56 oz (17 g) Peel here for drug facts

ECO SPF30 SUN STICK

spf30 broad spectrum sun stick stick

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58418-274

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	4 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0 X)	
ROSMARINUS OFFICINALIS FLOWERING TOP OIL (UNII: OXN0D3N28L)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	

CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
COCONUT OIL (UNII: Q9L0O73W7L)	
APIS CERANA WORKER SECRETION (UNII: PRG8653U8K)	
COCOA BUTTER (UNII: 512OYT1CRR)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58418-274-05	15 mL in 1 CANISTER; Type 0: Not a Combination Product	08/27/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2014	

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(58418-274)