

LAND SHARK SPF 30 TINTED ZINC- zinc oxide and titanium dioxide cream
Tropical Seas, Inc.

Land Shark SPF 30 Tinted Zinc

Drug Facts

Active Ingredients

Zinc Oxide 7.5%

Titanium Dioxide 3.2%

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 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

Inactive Ingredients

aqueous extracts of: butterfly nectars (buddleja davidii), thymus vulgaris (thyme), caprylic capric triglyceride, cyclopentasiloxane (and) c30-45 alkylcetearyl dimethicone crosspolymer, c13-16 isoparaffin, c12-14 iso-parraffin, aluminum hydroxide, c13-15 alkane, isostearic acid, octyldodecyl neopentanoate, glycerin, cyclopentasiloxane (and) peg/ppg-20/15 dimethicone, phenoxyethanol, caprylyl glycol, sorbic acid, sodium chloride, sorbitan leate, perfluorodecalin (o2), tetrasodium edta, and micas and/or iron oxides.

Other Information

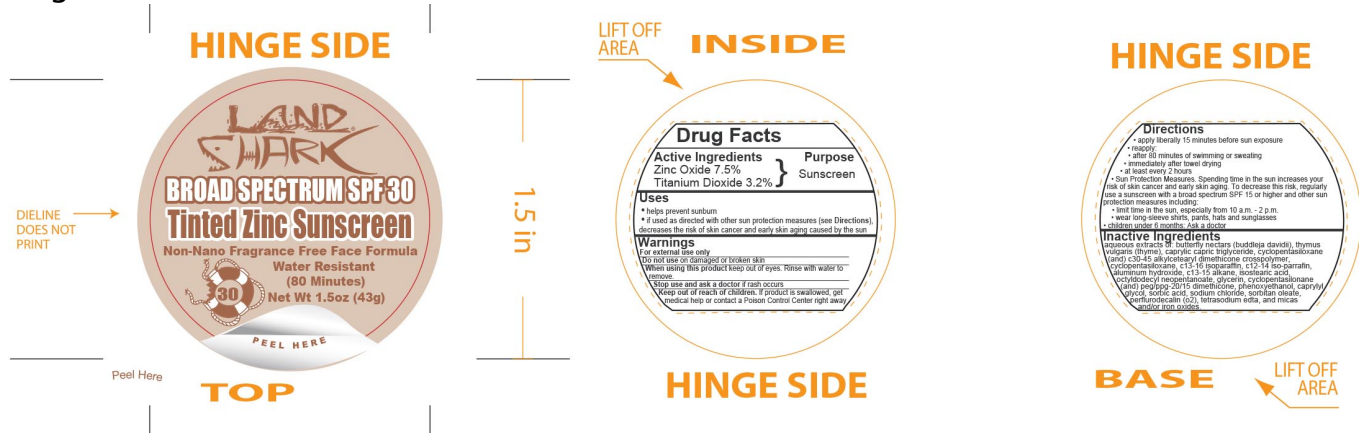
- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-800-368-7327

Principal Display Panel - 43 g Jar Label

43g NDC 52854-944-01



LAND SHARK SPF 30 TINTED ZINC

zinc oxide and titanium dioxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52854-944 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 7.5 g in 100 g |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 3.2 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| MICA (UNII: V8A1AW0880) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| WATER (UNII: 059QF0KO0R) | |
| BUDDLEJA DAVIDII LEAF (UNII: X380815D32) | |
| THYMUS VULGARIS LEAF (UNII: GRX3499643) | |
| CAPRYLIC/CAPRIC ACID (UNII: DI775RT244) | |
| DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6) | |
| C13-16 ISOPARAFFIN (UNII: LED42LZG6O) | |
| C12-14 ISOPARAFFIN (UNII: WP37Z9V66A) | |
| C13-15 ALKANE (UNII: 114P5I43UJ) | |
| ISOSTEARIC ACID (UNII: X33R8U0062) | |
| PEG/PPG-20/15 DIMETHICONE (UNII: 06R6X77P9C) | |
| BIS-PHENYLPROPYL DIMETHICONE (15 CST) (UNII: 4836494CFT) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T) | |
| PERFLUOROMETHYLDECALIN (UNII: VMJ68OB6TM) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| SORBIC ACID (UNII: X045VM989B) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SORBITAN MONOOLEATE (UNII: 06XEA2VD56) | |
| DITETRACYCLINE TETRASODIUM EDETATE (UNII: WX0A0IT7K5) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:52854-944-01 | 43 g in 1 JAR; Type 0: Not a Combination Product | 10/18/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 10/18/2021 | |

Labeler - Tropical Seas, Inc. (627865660)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|------------------------|
| Tropical Seas, Inc. | | 627865660 | manufacture(52854-944) |

Revised: 10/2023

Tropical Seas, Inc.