

LAND SHARK SPF 30 SUNKISSED- zinc oxide and titanium dioxide lotion
Tropical Seas, 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.

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: coconut (coco nucifera) water, butterfly nectars (buddleja davidii), thymus vulgaris (thyme), aloe barbadensis leaf extract, algae extract (hawaiian seaplant), chamomilla recutita (matricaria)

flower extract, symphytum officinale (comfrey) root & leaf extract, taraxacum officinale (dandelion) leaf extract, echinacea purpurea (coneflower) extract, sambucus nigra (elder) flower extract, panax quinquefolium (ginseng) root extract, macrocystis pyrifera (kelp) extract, lavandula angustifolia (lavender) extract, cymbopogon schoenanthus (lemon grass) extract, althea officinalis (marshmallow) root extract, achillea millefolium (yarrow flower) extract, camellia sinensis (white tea) extract, caprylic capric triglyceride, cyclopentasiloxane (and) c30-45 alkylcetearyl dimethicone crosspolymer, c13-16 isoparaffin, c12-14 iso-paraffin, c13-15 alkane, isostearic acid, cyclopentasiloxane (and) peg/ppg-20/15 dimethicone, cyclopentasiloxane, bis-phenylpropyl dimeticone, glycerin (coconut derived), octyldodecyl neopentanoate, perfluorodecalin (o2), phenoxyethanol, caprilyl glycol, sorbic acid, sodium chloride, micas and/or ironoxides, sorbitan oleate, and tetrasodium edta.

Other Information

- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-800-368-7327

Principal Display Panel - 120 mL Bottle Label

Land Shark™

Broad Spectrum SPF 30

30

O² Renew® Anti-Aging

Tinted: SunKissed

Water Resistant (80 Minutes)

Paraben Free • Biodegradable

Mineral Based **Sunscreen Lotion**

Made with Butterfly Nectars

4 fl. oz. (120ml)

Land Shark™



BROAD SPECTRUM SPF 30



O² Renew® Anti-Aging
Tinted: SunKissed

Water Resistant (80 Minutes)

Paraben Free • Biodegradable

Mineral Based Sunscreen Lotion



Made with



Butterfly Nectars

4 fl. oz. (120ml)

LAND SHARK SPF 30 SUNKISSED

zinc oxide and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52854-931
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 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3.2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
COCONUT WATER (UNII: 267F5Y81NT)	
BUDDLEJA DAVIDII LEAF (UNII: X380815D32)	
THYMUS VULGARIS LEAF (UNII: GRX3499643)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
CHAMOMILE (UNII: FGL3685T2X)	
SYMPHYTUM UPLANDICUM LEAF (UNII: D05HXK6R3G)	
COMFREY ROOT (UNII: M9VVZ08EKQ)	
TARAXACUM OFFICINALE LEAF (UNII: 0022LFFJ74Y)	
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)	
SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T)	
AMERICAN GINSENG (UNII: 8W75VCV53Q)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)	
CYMOPOGON SCHOENANTHUS TOP (UNII: 9SJ1LW39W)	
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAPRYLIC/CAPRIC ACID (UNII: DI775RT244)	
DIMETHICONE CROSSPOLYMER (45000 MPAS 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: VWJ68OB6TM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBIC ACID (UNII: X045WJ989B)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MICA (UNII: V8A1AW0880)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
DITETRACYCLINE TETRASODIUM EDETATE (UNII: WX0A0IT7K5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52854-931-01	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2017	
2	NDC:52854-931-02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/25/2017	

Labeler - Tropical Seas, Inc. (627865660)

Establishment

Name	Address	ID/FEI	Business Operations
Tropical Seas, Inc.		627865660	manufacture(52854-931)

Revised: 3/2020

Tropical Seas, Inc.