

LAND SHARK SPF 15- octocrylene, octisalate, and avobenzone lotion
Tropical Seas, Inc.

Land Shark SPF 15 Lotion

Drug Facts

Active Ingredients

Octocrylene 3.0%

Octisalate 2.0%

Avobenzone 1.0%

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: 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, phenethyl benzoate, octyl dodecyl citrate crosspolymer, stearic acid, glyceryl stearate se, cetyl dimethicone, glycerin, sodium hydroxide, emulsifying wax, tricontanyl-pvp, polyethylene, acrylates/c10-30 alkyl acrylates cross-polymer, cetyl alcohol, methylparaben, diazolidinyl urea, propylparaben, and caprylyl glycol.

Other Information

- protect this product from excessive cold, heat, and direct sun

Questions or comments?

Call toll free 1-800-368-7327

Principal Display Panel

192 ml NDC: 52854-915-01

LAND SHARK



**Dermatologist Tested
Hypoallergenic**

SPF 15

Broad Spectrum

Water Resistant (80 minutes)

Sunscreen Lotion

6.5 fl. oz. (192ml)

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Other Information

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Questions or comments?

Call toll free 1-800-368-7327

079608 91156

Made in the U.S.A.
by: **Tropical Seas**
Ormond Beach, FL 32179
1-800-368-SEAS (7327)
www.tropicalseas.com



LAND SHARK SPF 15

octocrylene, octisalate, and avobenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52854-915
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CARRAGEENAN (UNII: 5C69YCD2YJ)
CHAMOMILE (UNII: FGL3685T2X)
SYMPHYTUM UPLANDICUM LEAF (UNII: D05HXX6R3G)
COMFREY ROOT (UNII: M9VVZ08EKQ)
TARAXACUM OFFICINALE LEAF (UNII: 0022LFJ74Y)
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)
SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T)
AMERICAN GINSENG (UNII: 8W75VCV53Q)
MACROCYSTIS PYRIFERA (UNII: K31S30G5C4)
LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)
CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJI1LW39W)
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
PHENETHYL BENZOATE (UNII: 0C143929GK)
STEARIC ACID (UNII: 4ELV7Z65AP)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)
GLYCERIN (UNII: PDC6A3C0OX)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
POLYSORBATE 60 (UNII: CAL22UVI4M)
TRICONTANYL POVIDONE (UNII: N0SS3Q238D)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)
CETYL ALCOHOL (UNII: 936JST6JCN)
METHYLPARABEN (UNII: A2I8C7HI9T)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52854-915-01	192 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/14/2020	

Labeler - Tropical Seas, Inc. (627865660)

Establishment

Name	Address	ID/FEI	Business Operations
Tropical Seas, Inc.		627865660	manufacture(52854-915)

Revised: 10/2023

Tropical Seas, Inc.