

LAND SHARK SPF 8- octinoxate and oxybenzone oil
Tropical Seas, Inc.

Drug Facts

Active Ingredients

Octinoxate 5.0%

Oxybenzone 2.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown to prevent sunburn, not skin cancer or early skin aging.

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
- children under 6 months: Ask a doctor

Inactive Ingredients

mineral oil, ethylhexyl palmitate, cocos nucifera (coconut) oil, simmondsia chinensis (jojoba) oil, theobroma cacao (cocoa) seed butter, fragrance, and propylparaben.

Other Information

- hold approximately 10 - 12 inches from skin to spray
- spray into palm of hand, rub together, then apply to your face
- do not spray directly into your face so that it won't get in your eyes.
- rub into skin evenly to ensure appropriate coverage
- this product provides minimum sunburn protection
- fair skin types should use a higher spf
- protect this product from excessive cold, heat, and direct sun

Questions or comments?

Call toll free 1-800-368-7327

Principal Display Panel - Bottle Label

250 ml NDC: 52854-928-01

LAND SHARK SPF 8 oil

LAND SHARK

SPF 8

island formula

Darker
Tanning Oil

Water Resistant (80 minutes)
Enriched with Cocoa Butter

8.45 fl. oz. (250ml)

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MADE IN
USA

Made in the U.S.A.
by: *Tropical Seas*[®]
Ormond Beach, FL 32173
1-800-368-SEAS (7327)
www.tropicalesas.com

LAND SHARK SPF 8

octinoxate and oxybenzone oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52854-928
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
COCONUT OIL (UNII: Q9L0O73W7L)	
JOJOBA OIL (UNII: 724GKU717M)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
COCOA BUTTER (UNII: 512OYT1CRR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52854-928-01	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/22/2020	

Labeler - Tropical Seas, Inc. (627865660)

Establishment

Name	Address	ID/FEI	Business Operations
Tropical Seas, Inc.		627865660	manufacture(52854-928)