

**LAND SHARK SPF 45- octocrylene, octinoxate, oxybenzone, homosalate and octisalate lotion**  
**Tropical Seas, Inc.**

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**Drug Facts**

**Active Ingredients**

Octocrylene 8.0%

Octinoxate 7.5%

Oxybenzone 6.0%

Homosalate 5.0%

Octisalate 5.0%

**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

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, stearic acid (vegetable derived), glyceryl stearate se (vegetable derived), titanium dioxide, cetyl dimethicone, glycerin (coconut derived), sodium hydroxide, emulsifying wax (vegetable derived), tricontanyl-pvp, polyethylene, acrylates/c10-30 alkyl acrylates cross-polymer, methylparaben, cetyl alcohol (vegetable derived), diazolidinyl urea and propylparaben.

## Other Information

- protect this product from excessive heat and direct sun

## Questions or comments?

Call toll free 1-800-368-7327

## Principal Display Panel - Bottle Label

120 ml NDC: 52854-945-01





# SPF45

**Original Formula**

**Water Resistant (80 minutes)**

**Sunscreen Lotion**

**4 fl. oz. (120ml)**

**Dermatologist Tested**

Fragrance Free • Dermatologist Tested



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

## LAND SHARK SPF 45

octocrylene, octinoxate, oxybenzone, homosalate and octisalate lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52854-945
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 g in 100 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
<b>SYMPHYTUM UPLANDICUM LEAF</b> (UNII: D05HXX6R3G)	
<b>COMFREY ROOT</b> (UNII: M9VVZ08EKQ)	
<b>TARAXACUM OFFICINALE LEAF</b> (UNII: 0022LFJ74Y)	
<b>ECHINACEA, UNSPECIFIED</b> (UNII: 4N9P6CC1DX)	
<b>SAMBUCUS NIGRA FLOWER</b> (UNII: 07V4DX094T)	
<b>AMERICAN GINSENG</b> (UNII: 8W75VCV53Q)	
<b>MACROCYSTIS PYRIFERA</b> (UNII: K31S30G5C4)	
<b>LAVANDULA ANGUSTIFOLIA FLOWERING TOP</b> (UNII: 9YT4B71U8P)	
<b>CYMBOPOGON SCHOENANTHUS TOP</b> (UNII: 9SJ11LW39W)	
<b>ALTHAEA OFFICINALIS ROOT</b> (UNII: TRW2FUF47H)	
<b>ACHILLEA MILLEFOLIUM FLOWER</b> (UNII: YQR8R0SQEA)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>CETYL DIMETHICONE 150</b> (UNII: 5L694Y0T22)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>TRICONTANYL POVIDONE</b> (UNII: N0SS3Q238D)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 809Y72KV36)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52854-	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a	07/22/2020	

945-01	Combination Product	07/22/2020	
<b>Marketing Information</b>			
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(52854-945)

Revised: 10/2023

Tropical Seas, Inc.