

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

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**Drug Facts**

**Active Ingredients**

Octinoxate 4.5%

Oxybenzone 1.5%

**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, 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, glyceryl stearate se, cetyl dimethicone, glycerin, tricontanyl-pvp, polyethylene, cetyl alcohol, methylparaben, propylparaben, diazolidinyl urea, fragrance, sodium hydroxide, acrylates/c10-30 alkyl acrylates cross-polymer, and theobroma cacao (cocoa) seed butter.

**Other Information**

- protect this product from excessive heat and direct sun

**Questions or comments?**

Call toll free 1-800-368-7327

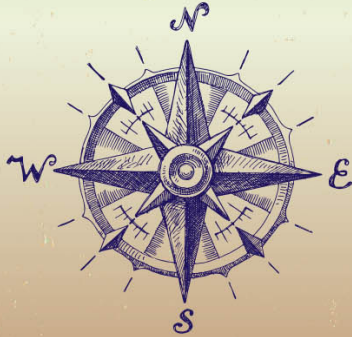
**Principal Display Panel - Bottle Label**

192 ml NDC: 52854-908-01



**SPF 8**

*island formula*



**Darker  
Tanning Lotion**

Water Resistant (80 minutes)

Enriched with Cocoa Butter

6.5 fl. oz. (192ml)

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**Other Information**  
• 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

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

**upcc**  
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**LAND SHARK SPF 8**

octinoxate and oxybenzone lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52854-908
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4.5 g in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1.5 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: K31S3OG5C4)
<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)
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52854-908-01	192 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**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Tropical Seas, Inc.		627865660	manufacture(52854-908)

Revised: 10/2023

Tropical Seas, Inc.