LAND SHARK SPF 50- octocrylene, octisalate, and avobenzone lotion Tropical Seas, Inc.

Land Shark SPF 50 Oxy Free

Drug Facts

Active Ingredients

Octocrylene 10.0%

Octisalate 5.0%

Avobenzone 3.0%

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

60 ml NDC: 52854-950-01

120 ml NDC: 52854-950-02

2 fl. oz. (60ml)

Drug Facts

Active Ingredients Octocrylene 10.0% Octisalate 5.0% Avobenzone 3.0%

Purpose Sunscreen

Uses

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Stop use and ask a doctor if rash occurs

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Directions

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- wear long-sleeve shirts, pants, hats and sunglasses children under 6 months: Ask a doctor

Inactive Ingredients

aqueous extracts of: aloe barbadensis leaf extract, aqueous extract, chamomilla recutita (matricaria) flower extract, symphytum officinale (comfrey) root & leaf extract, taraxacum officinale (dandelion) leaf extract, extract, taraxacum officinate (uanuelini) near 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, 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, allantoin, sodium hydroxide, emulsifying wax, tricontanyl-pvp, polyethylene, acrylates/c10-30 alkyl acrylates cross-polymer, cetyl alcohol, methylparaben, diazolidriu urae, pronylazaben, and cappylyl olycol. diazolidinyl urea, propylparaben, and caprylyl glycol

Other Information

· protect this product from excessive cold, heat and direct

Questions or comments?

Call toll free 1-800-368-7327

www.tropicalseas.com







Drug Facts

Active Ingredients
Octocrylene 10.0%
Octisalate 5.0%



Purpose Sunscreen

- 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

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Directions

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 - immediately after towel drying
- at least every 2 hours
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 - 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, allantoin, 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

Made in the Tropical Seas®

U.S.A.

by:

Ormond Beach, FL 32173

1-800-368-SEAS (7327)

www.tropicalseas.com



192 ml NDC: 52854-950-03



Drug Facts

Active Ingredients Octorrvlene 10.0%

Octisalate 5.0% Avobenzone 3.0%

Purpose Sunscreen

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

Directions

- apply liberally 15 minutes before sun exposure
 reapply:
 alter 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:

 In imit 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

children under 6 months: Ask a doctor

Inactive Ingredients
aqueous extracts of aloe barbadensis leaf extract, algae
extract (hawaiian seaplant), chamomilia recultal (matricaria)
flower extract, symphylum officinale (comfrey) root & leaf
extract, traxaccum 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 eschoenanthus
(lemon grass) extract, atimea officinalis (marshmailow) root
extract, achillea millefolium (varrow flower) extract, camellia
sinensis (white tea) extract, phenetryl benzoate, octyl dodecyl
citrate crosspoymer, stearie acid (plant derived), glycerin (plant
derived), allantoin, sodium hydroxide, emulsyling wax (plant
derived), tircontamy-pvp, polyethylene, acrylates/c10-30 alkyl
acrylates cross-polymer, celyl alacoho (plant derived),
methylparaben (flood grade), diazoidinyl urea, propylparaben
(flood grade), and caprylyl glycol.

Other Information

Other Information

Questions or comments?









- 1-800-368-SEAS (7327) www.tropicalseas.com Ormond Beach, FL 3217

946 ml NDC: 52854-950-04



Broad Spectrum

Water Resistant (80 minutes)

Sunscreen Lotion

32 fl. oz. (946ml)

3785 ml NDC: 52854-950-05

Drug Facts

Active Ingredients

Octocrylene 10.0% Octisalate 5.0% Avobenzone 3.0%

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

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 (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, allantoin, 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 sur

Questions or comments?

Call toll free 1-800-368-7327

U.S.A.

by:

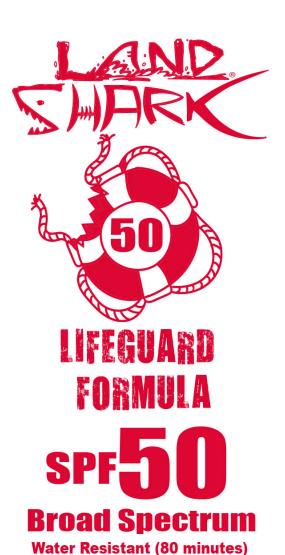
Made in the **Tropical Seas** Ormond Beach, FL 32173

1-800-368-SEAS (7327)

www.tropicalseas.com

0 79608 91503





128 fl. oz. (3785ml)

Sunscreen Lotion

Drug Facts

Active Ingredients Octocrylene 10.0% Octisalate 5.0% Avobenzone 3.0%

Purpose Sunscreen

9608

- 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

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

Directions

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 after 80 minutes of swimming or sweating
 immediately after towel drying
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- 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

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, glyceryi stearate se, cetyl dimethicone,
glycerin, allantoin, sodium hydroxide, emulsifying wax,
tricontanyl-pyp, polyethylene, acrylates/c10-30 alkyl
acrylates cross-polymer, cetyl alcohol, methylparaben,
diazolidinyl urea, propylparaben, and caprylyl glycol.

Other Information

Questions or comments?

Call toll free 1-800-368-7327

U.S.A.

Made in the **Tropical Seas**® Ormond Beach, FL 32173

by: 1-800-368-SEAS (7327)

www.tropicalseas.com

LAND SHARK SPF 50

octocrylene, octisalate, and avobenzone lotion

Product Information

Product Type HUMAN OTC DRUG NDC:52854-950 Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
CHAMOMILE (UNII: FGL3685T2X)	
SYMPHYTUM UPLANDICUM LEAF (UNII: D05HXK6R3G)	
COMFREY ROOT (UNII: M9VVZ 08EKQ)	
TARAXACUM OFFICINALE LEAF (UNII: 0022LFJ74Y)	
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)	
SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T)	
AMERICAN GINSENG (UNII: 8W75VCV53Q)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
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: Z8IX2SC10H)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Packaging					
#	Item Code Package Description Marketing Sta		Marketing Start Date	t Marketing End Date	
1	NDC:52854- 950-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/29/2020		
2	NDC:52854- 950-02	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/2020		
3	NDC:52854- 950-03	192 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/14/2020		
4	NDC:52854- 950-04	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/29/2020		
5	NDC:52854- 950-05	3785 mL in 1 JUG; Type 0: Not a Combination Product	06/29/2020		

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(52854-950)	

Revised: 10/2023 Tropical Seas, Inc.