LAND SHARK SPF 30- octocrylene, octisalate, avobenzone lipstick Tropical Seas, Inc.

Lip Balm Sangria SPF 30

Drug Facts

Active Ingredients

Octocrylene 5.0%

Octisalate 3.0%

Avobenzone 2.5%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- helps prevent chapped or cracked skin

Warnings

For external use only *Keep out of eyes

Stop use and ask a doctor if rash occurs

Keep out of reach of children.

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

ricinus communis (castor) seed oil, cetearyl alcohol, lauryl laurate, olea europaea (olive)

fruit oil, hydrogenated castor oil, beeswax, copernicia cerifera (carnauba) wax, flavor, hydrogenated soybean oil, euphorbia cerifera (candelilla) wax, flavor, glyceryl stearate, octyl dodecyl citrate crosspolymer, phenethyl benzoate, cocos nucifera (coconut) fruit extract, octyldodecyl neopentanoate, cetyl dimethicone, hippophae rhamnoides (sea buckthorn) oil.

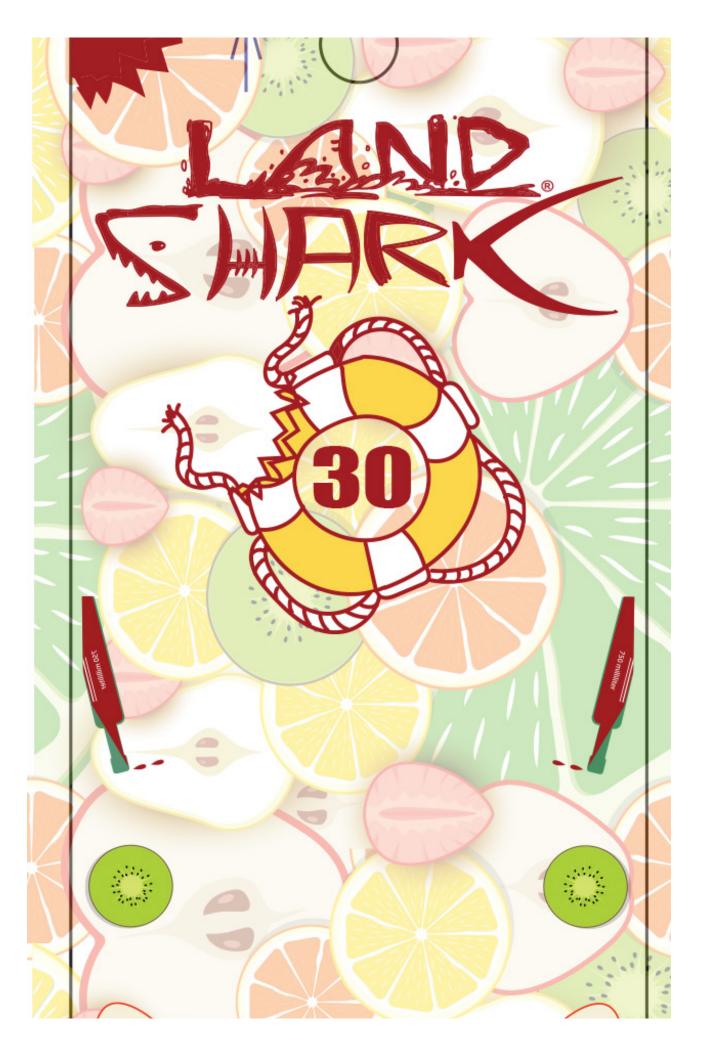
Principal Display Panel - Label

4.44g NDC 52854-981-01

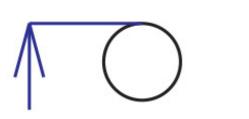


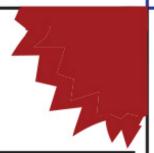
4.44g NDC 52854-981-01 Blister Card Front











Drug Facts

Active Ingredients

Octocrylene 5.0%
Octisalate 3.0%
Avobenzone 2.5%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- helps prevent chapped or cracked skin
- 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

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.
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Inactive Ingredients

ricinus communis (castor) seed oil, cetearyl alcohol, lauryl laurate, olea europaea (olive) fruit oil, hydrogenated castor oil, beeswax, copernicia cerifera (carnauba) wax, flavor, hydrogenated soybean oil, euphorbia cerifera (candelilla) wax, glyceryl stearate, octyl dodecyl citrate crosspolymer, phenethyl benzoate, cocos nucifera (coconut) fruit extract, octyldodecyl neopentanoate, cetyl dimethicone, hippophae rhamnoides (sea buckthorn) oil.

Other Information

protect this product from excessive heat and direct sun

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





LAND SHARK SPF 30

octocrylene, octisalate, avobenzone lipstick

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52854-981	

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 g	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 g in 100 g	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.5 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
CASTOR OIL (UNII: D5340Y2I9G)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
LAURYL LAURATE (UNII: GPW77G0937)			
OLIVE OIL (UNII: 6UYK2W1W1E)			
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)			
CANDELILLA WAX (UNII: WL0328HX19)			
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)			
PHENETHYL BENZOATE (UNII: 0C143929GK)			
COCONUT (UNII: 3RT3536DHY)			
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)			
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)			
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

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OTC Monograph Dru	M020	08/03/2020	
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Marketing Information			
	4.44 g in 1 TUBE; Type 0: Not a Combination Product	08/03/2020	

Labeler - Tropical Seas, Inc. (627865660)

Establishment				
Name	Address	ID/FEI	Business Operations	
Tropical Seas, Inc.		627865660	manufacture(52854-981)	

Revised: 10/2023 Tropical Seas, Inc.