

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

LAND SHARK®

SANGRIA

Broad Spectrum SPF 30 LIP BALM

Drug Facts

Active Ingredients	Purpose
Octocrylene 5.0%	Sunscreen
Octisalate 3.0%	
Avobenzone 2.5%	

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

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, and hippophae rhamnoides (sea buckthorn) oil.

NT WT. .15 oz. (4.44 gm)

TWIST CAP TO BREAK SEAL

Sealed for your protection

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

4.44g NDC 52854-981-01 Blister Card Front



LAND SHARK

30



The background is a vibrant collage of various fruit slices, including lemons, oranges, kiwis, and pomegranates. Interspersed among the fruit are several stylized lip balm containers, some of which are open, showing the product inside. The overall theme is fresh, fruity, and natural.

SANGRIA **Broad Spectrum** **SPF 30** **LIP BALM**

Net Weight .15 oz. (4.44 gm)



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:
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Other Information

- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-800-368-7327

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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: Z F94AP8MEY)	
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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1	NDC:52854-981-01	4.44 g in 1 TUBE; Type 0: Not a Combination Product	08/03/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020		08/03/2020	

Labeler - Tropical Seas, Inc. (627865660)

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