

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

Lip Balm Unflavored 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 52854-927-01

LAND SHARK
UNFLAVORED
Broad Spectrum
SPF 30 LIP BALM

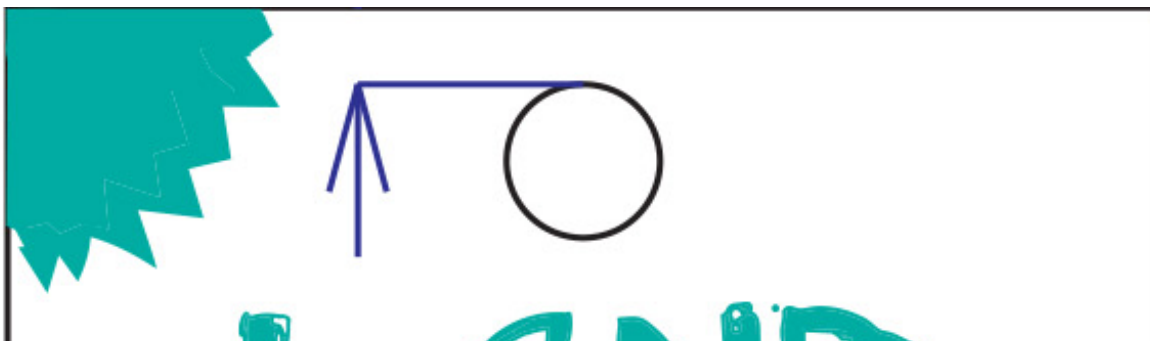
Sealed for your protection
TWIST CAP TO BREAK SEAL

NT WT. .15 oz. (4.44 gm)

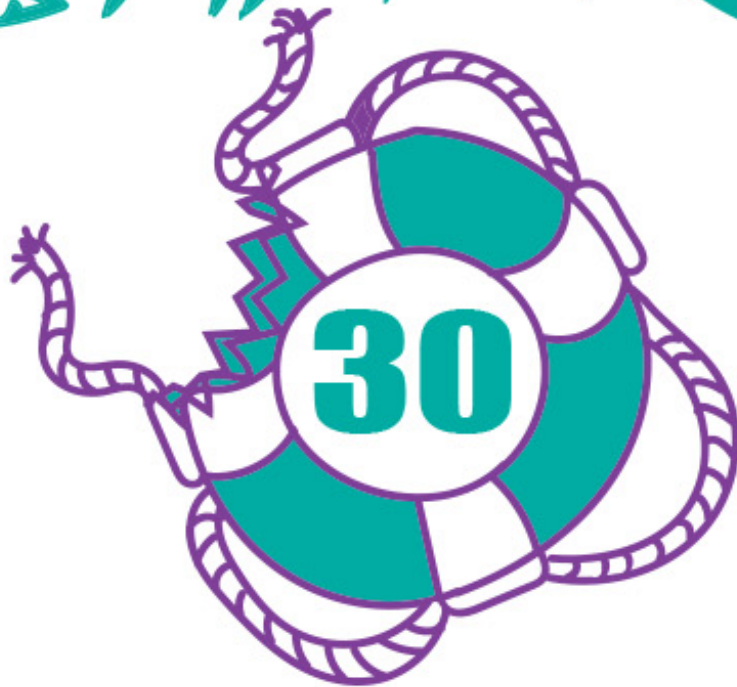
| Drug Facts | |
|--|----------------|
| Active Ingredients | Purpose |
| Octocrylene 5.0% | } Sunscreen |
| Octisalate 3.0% | |
| Avobenzone 2.5% | |
| Uses •helps prevent sunburn •helps prevent chapped or cracked skin | |
| Warnings •For external use only •Keep out of eyes •Stop use and ask a doctor 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, hydrogenated soybean oil, euphorbia cerifera (candelilla) wax, glyceryl stearate, octyl dodecyl citrate crosspolymer, phenethyl benzoate, cocos nucifera (coconut) fruit extract, octyldodecyl neopentanoate, and cetyl dimethicone. | |

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

4.44g NDC 52854-927-01 Blister Card Front



LAND SHARK





UNFLAVORED
Broad Spectrum
SPF 30
LIP BALM
Net Weight .15 oz. (4.44 gm)

4.44g NDC 52854-927-01 Blister Card Back

Dove

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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- children under 6 months: Ask a doctor

Inactive Ingredients

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ricinus communis (castor) seed oil, cetearyl alcohol, lauryl laurate, olea europaea (olive) fruit oil, hydrogenated castor oil, beeswax, copernicia cerifera (carnauba) wax, 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

Made in the *Tropical Seas*[®]
U.S.A. Ormond Beach, FL 32173
by: 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:52854-927 |
| 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 |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:52854-927-01 | 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(52854-927) |

Revised: 10/2023

Tropical Seas, Inc.