

**EXPEDITION BACKCOUNTRY 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

Expedition BackCountry
Unflavored Broad Spectrum SPF 30 Lip Balm
 Water Resistant (80 minutes)

Lot#XXXX

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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

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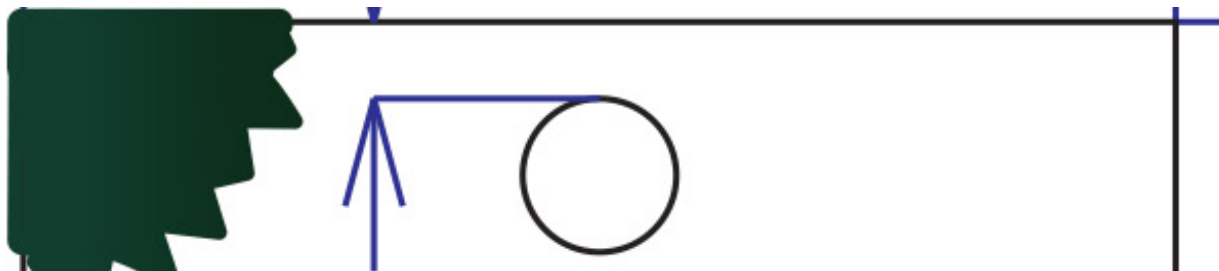
NT WT. .15 oz. (4.44 gm)

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

0 79608 91796 6

Sealed for your protection
 TWIST CAP TO BREAK SEAL

4.44g NDC 52854-927-01 Blister Card Front

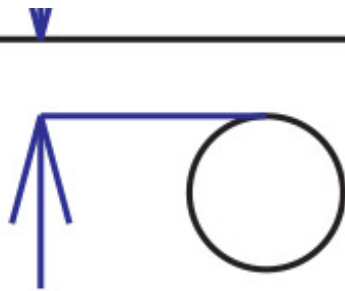






Unflavored
Broad Spectrum
SPF 30 Lip Balm
Water Resistant (80 minutes)

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:
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 - 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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U.S.A.
by:

Tropical Seas[®]

Ormond Beach, FL 32173

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www.tropicalseas.com





EXPEDITION BACKCOUNTRY SPF 30

octocrylene, octisalate, avobenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52854-976
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:52854-976-01	4.44 g in 1 TUBE; Type 0: Not a Combination Product	08/10/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/10/2023	

Labeler - Tropical Seas, Inc. (627865660)

Establishment

Name	Address	ID/FEI	Business Operations
Tropical Seas, Inc.		627865660	manufacture(52854-976)

Revised: 10/2023

Tropical Seas, Inc.