

**EXPEDITION BACKCOUNTRY SPF 50- octocrylene, octisalate, and avobenzone lotion**  
**Tropical Seas, Inc.**

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**Expedition BackCountry SPF 50**

**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: 52854-952-01

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**Other Information**

- protect this product from excessive cold, heat, and direct sun
- store at temp below 90° F and avoid long term storage
- may stain fabrics or surfaces

**Questions or comments?**  
Call toll free 1-800-368-7327

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Tropical Seas  
Ormond Beach, FL 32173  
1-800-368-SEAS (7327)  
www.tropicalseas.com

## EXPEDITION BACKCOUNTRY SPF 50

octocrylene, octisalate, and avobenzone lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52854-952
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	

<b>CHAMOMILE</b> (UNII: FGL3685T2X)
<b>SYMPHYTUM UPLANDICUM LEAF</b> (UNII: D05HXK6R3G)
<b>COMFREY ROOT</b> (UNII: M9VVZ08EKQ)
<b>TARAXACUM OFFICINALE LEAF</b> (UNII: 0022LFJ74Y)
<b>ECHINACEA, UNSPECIFIED</b> (UNII: 4N9P6CC1DX)
<b>SAMBUCUS NIGRA FLOWER</b> (UNII: 07V4DX094T)
<b>AMERICAN GINSENG</b> (UNII: 8W75VCV53Q)
<b>MACROCYSTIS PYRIFERA</b> (UNII: K31S30G5C4)
<b>LAVANDULA ANGUSTIFOLIA FLOWERING TOP</b> (UNII: 9YT4B71U8P)
<b>CYMBOPOGON SCHOENANTHUS TOP</b> (UNII: 9SJ11LW39W)
<b>ALTHAEA OFFICINALIS ROOT</b> (UNII: TRW2FUF47H)
<b>ACHILLEA MILLEFOLIUM FLOWER</b> (UNII: YQR8R0SQEA)
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)
<b>PHENETHYL BENZOATE</b> (UNII: 0C143929GK)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)
<b>CETYL DIMETHICONE 150</b> (UNII: 5L694Y0T22)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)
<b>TRICONTANYL POVIDONE</b> (UNII: N0SS3Q238D)
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)
<b>CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 809Y72KV36)
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52854-952-01	60 mL in 1 BOTTLE, PLASTIC; 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(52854-952)

