

**FRESH COAST SPF 50 SUNSCREEN- avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% lotion**  
**Derma Care Research Labs, LLC**

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**Fresh Coast SPF 50 Sunscreen Lotion**

**Active Ingredients**

Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%

**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 eyes with water to remove.

**Stop use and ask a doctor if** rash occurs.

**Keep Out of Reach of Children.**

If 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 risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measure including:

- limit time in the sun, especially from 10 am to 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

## Inactive Ingredients

Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Phenoxyethanol, Polyglyceryl-3 Methylglucose Distearate, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water

## Label



The label features a circular logo with a sunset scene, a sailboat, and birds. The text 'FRESH COAST SUNSCREEN' is arched around the logo. Below the logo is a pink box with 'SPF 50'. The main body of the label is blue and contains the following text:

**Fresh Formula  
Smells Like Sunscreen**

**FACE & BODY LOTION - UNTINTED  
BROAD SPECTRUM SPF 50  
WATER RESISTANT (80 MINUTES)  
OXYBENZONE FREE  
REEF FRIENDLY**

**Net Wt. 5 Oz (142 g)**

**Drug Facts**

Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 15%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 10%	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 or irritation develops and lasts.  
**Keep out of the 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 value of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 a.m.-2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses. • children under 6 months of age: ask a doctor.

**Other information** • protect the product in this container from excessive heat and direct sun • may stain fabrics.

**Inactive ingredients** Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Phenoxyethanol, Polyglyceryl-3 Methylglucose Distearate, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water.

DISTRIBUTED BY:  
FRESH COAST SUNSCREEN  
GRAND RAPIDS, MI 49546  
FRESHCOASTSUNSCREEN.COM  
INFO@FRESHCOASTSUNSCREEN.COM  
855-DAILYSPF

ITEM #308  
USA AND INTERNATIONAL COMPONENTS

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## FRESH COAST SPF 50 SUNSCREEN

avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72839-135
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 g

<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ006294)	
<b>DIMETHICONE 200</b> (UNII: RGS4T2AS00)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>POLYGLYCERYL-3 METHYLGLUCOSE DISTEARATE</b> (UNII: W19EIO0DBE)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
<b>EICOSYL POVIDONE</b> (UNII: XQQ9MKE2BJ)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-135-05	142 g in 1 TUBE; Type 0: Not a Combination Product	05/26/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/26/2022	

**Labeler** - Derma Care Research Labs, LLC (116817470)

**Registrant** - Derma Care Research Labs, LLC (116817470)

### Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs		116817470	manufacture(72839-135)