

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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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 central circular logo with a sunset scene, a sailboat, and birds. The text 'FRESH COAST SUNSCREEN' is arched around the top and bottom of the circle. Below the logo is a pink box with 'SPF 50'. The background is split into light blue and teal sections.

**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 49516
FRESHCOASTSUNSCREEN.COM
INFO@FRESHCOASTSUNSCREEN.COM
855-DAILYSPF

ITEM #308
USA AND INTERNATIONAL COMPONENTS

1-96652-57308-0

Facebook, Twitter, Instagram icons

FRESH COAST SPF 50 SUNSCREEN

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

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
DIMETHICONE 200 (UNII: RGS4T2AS00)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYGLYCERYL-3 METHYLGLUCOSE DISTEARATE (UNII: W19EIO0DBE)	
TROLAMINE (UNII: 9O3K93S3TK)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	
SORBITOL (UNII: 506T60A25R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (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 not final	part352	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)

