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 n 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:

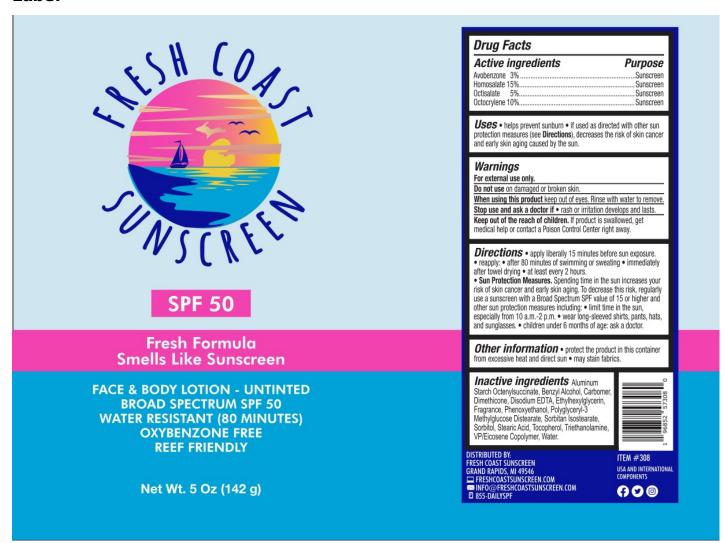
• limit time in the sun, especially from 10 am to 2 pm

- 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



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: 19PJ006294)		
DIMETHICONE 200 (UNII: RGS4T2AS00)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
POLYGLYCERYL-3 METHYLGLUCOSE DISTEARATE (UNII: W19EIO0DBE)		
TROLAMINE (UNII: 903K93S3TK)		
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 Application Number or Monograph Category 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)		