SEA AND SKI SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion Cross Brands Contract Filling

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.

Sea & Ski Reef-Friendly SPF 50 Lotion 1.5oz

Active ingredients



Avobenzone 3.0%, Homsalate 15.0%, Octisalate 7.0%, Octocrylene 8.0%

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 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 sweting immediately after towl 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: Ask a doctor.

Other Information



protect this product from excessive heat and direct sun may stain some fabrics, wood, plastics, vinyl for use on skin only store between 20°-25°C (68°-77°F).

Inactive ingredients



acrylates copolymer, acrylates/c10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, butylene glycol, carbomer, dimethicone, disodium EDTA, ethylhexyl palmitate, ethylhexylglycerin, fragrance, glycerin, hydroxypropyl methylcellulose, neopentyl glycol diheptanoate, phenoxyethanol, simmondsia chinensis (jojoba) extract, sorbitan monooleate, styrene/ acrylates

Questions or comments?



Call 855-sea-n-ski (855-732-6754) or visit www. seaNski.com

Package Label



SEA AND SKI SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73440-2156	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.275 g in 42.5 g		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	6.375 g in 42.5 g		
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.975 g in 42.5 g		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3.4 g in 42.5 g		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)	19.95 g in 42.5 g	

Product Characteristics			
Color	white (Opaque)	Score	
Shape		Size	
Flavor		Imprint Code	

Contains **Packaging Marketing Start Marketing End Item Code Package Description Date** Date **1** NDC:73440-2156-1 42.5 g in 1 TUBE; Type 0: Not a Combination 09/25/2020 Product **Marketing Information Application Number or Monograph Marketing Start Marketing End** Marketing Category Citation Date Date OTC monograph final part352 09/25/2020

Labeler - Cross Brands Contract Filling (117871824)

Establishment			
Name	Address	ID/FEI	Business Operations
Cross Brands Contract Filling		117871824	manufacture(73440-2156), label(73440-2156), pack(73440-2156)

Revised: 2/2021 Cross Brands Contract Filling