

GENERAL PROTECTION- avobenzene, homosalate, octinoxate, octisalate, octocrylene lotion
Cross-Brands Manufacturing 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.

Sea & Ski SPF 50 Tube

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SEA&SKI®
Anti-Aging Sunscreen Lotion SPF 50

Drug Facts	
Active ingredients	Purpose
Avobenzene 3.0%, Homosalate 10.0%, Octinoxate 7.5%, Octisalate 5.0%, Octocrylene 5.0%	} 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 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: 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.	
Inactive ingredients	
acrylates copolymer, acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, argania spinosa, ascorbic acid, carbomer, cholecalciferol, dimethicone, disodium EDTA, ethylhexyl palmitate, ethylhexylglycerin, fragrance, glycerin, hydroxypropyl methylcellulose, neopentyl glycol diheptanoate, octyldodecanol, PEG-16 macadamia glycerides, phenoxyethanol, propylene glycol, pyridoxine HCl, retinyl palmitate, silica, sodium propoxyhydroxypropyl thiosulfate silica, sorbitan mono oleate, styrene/acrylates copolymer, tocopheryl acetate, triethanolamine, water, zeamays (corn) oil	
Questions or comments? Call 855-sea-n-ski (855-732-6754) or visit www.seanski.com .	

Distributed by:
Cross-Brands Manufacturing, LLC
 1 South Orlando Ave.
 Cocoa Beach, FL 32931 *Made in U.S.A.*

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GENERAL PROTECTION

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71153-2013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71153-2013-1	44 mL in 1 TUBE; Type 0: Not a Combination Product	02/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/01/2017	

Labeler - Cross-Brands Manufacturing LLC (080319350)

Establishment

Name	Address	ID/FEI	Business Operations
Cross-Brands Manufacturing LLC		080319350	label(71153-2013) , manufacture(71153-2013)

Revised: 2/2017

Cross-Brands Manufacturing LLC