

GENERAL PROTECTION- avobenzene, octinoxate, octisalate, octocrylene gel
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 30 Dry Gel

Sea & Ski SPF 30 Dry Gel Tube

SEA & SKI

Beyond UV™

with IR-Guard™
Infrared Protection

Fragrance
Free

SPORT

ULTRA LIGHT
DRI-GEL
SUNSCREEN

30

Broad Spectrum SPF 30
WATER RESISTANT
(80 MINUTES)

1.5 FL OZ (44mL)

SEA & SKI®
Ultra Light DRI-GEL Sunscreen SPF 30

Drug Facts

Active ingredients Avobenzene 3.0%, Octinoxate 7.5%, Octisalate 3.0%, Octocrylene 2.0%	Purpose Sunscreen
Uses • helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun	
Warnings	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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 aloe barbadensis leaf juice, butylene glycol, dmdm hydantoin, iodopropynyl butylcarbamate, jojoba (simmondsia chinensis) extract, potassium hydroxide, PVM/MA, daciadiene crosspolymer, tocopherol (vitamin E), water, xanthan gum	
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.

avobenzone,octinoxate,octisalate,octocrylene gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71153-20 12
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	3 g in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	2 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
XANTHAN GUM (UNII: TTV12P4NEE)	
ALOE VERA LEAF (UNII: ZY8 1Z83H0 X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71153-20 12-1	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	manufacture(71153-20 12) , label(71153-20 12)

Revised: 2/2017

Cross-Brands Manufacturing LLC