

**ISLANDER SPF6- octinoxate, octisalate, avobenzone, octocrylene lotion**  
**Island Company Lifestyle Products, 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.*

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**islander spf6**

<b>Active Ingredients</b>	<b>Purpose</b>
Octinoxate 5.0%	Sunscreen
Octisalate 3.0%	Sunscreen
Oxybenzone 2.0%	Sunscreen
Avobenzone 2.0%	Sunscreen
Octocrylene 1.5%	Sunscreen

**Uses**

- Helps prevent sunburn
- Higher SPF gives more sunburn protection

**Warnings**

- For external use only
- Keep out of reach of children

**When using this product**

- Keep out of eyes. Rinse with water to remove

**Stop use and ask doctor if**

- Rash or irritation develops and lasts

**Directions**

- Apply liberally 20 minutes before sun exposure and as needed
- For children under 6 months of age: Ask a doctor

**Other Information**

Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun

**Inactive Ingredients**

Water, Adipic Acid/Diethylene Glycol Glycerin Crosspolymer, Polycrylene, Isopropyl Myristate, Fragrance, Propylene Glycol, Hydrogenated Polyisobutene, Polyethylene, Aloe Barbadensis Leaf Extract, Allantoin, Sodium Ascorbic Phosphate, Tocopheryl Acetate, Retinyl Palmitate, Cetyl Alcohol, Triethanolimine, C12-15 Alkyl Benzoate, Sorbitan Stearate, Acrylates/c10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Carbomer, Carpylyl Glycol, Disodium EDTA, Methylisothiazolinone



## islander® spf 6

### dark tanning lotion

Living in the islands like an islander means knowing the lingo and being able to advise the tourists on what to eat, where to drink and how to find the empty beaches. You are almost a local now which means your skin is already tan but you still respect the strong tropical sun with our **SPF 6 DARK TANNING LOTION**. Because every islander knows that to become a local you need a dark tan without ever getting burned like a tourist!

### colada recipe

ESCAPE TRAVEL LIVE®

8 FL. OZ./236 ML



### ENJOY THE TROPICS RESPONSIBLY

With an island blend of Cocoa Butter, Aloe, Vitamins A, C, E and our unique **colada recipe** of fragrance, this lotion will keep you yearning for the tropical islander lifestyle forever.

### WATERPROOF · UVA & UVB PROTECTION

**directions:** Please shake this bottle before use. Apply evenly 20 minutes prior to sun exposure. Reapply after lots of swimming, or excessive perspiration or if product has been removed from towel drying.

**WARNING:** External use only. Keep out of eyes. Rinse with water to remove. If irritation occurs stop use and seek medical advice. For children under 6 months of age ask a doctor.

**active ingredients:** Octinoxate, Octisalate, Avobenzone, Octocrylene.

Never tested on animals.

Designed by true island travelers.

### distributed by:

Island Company  
Lifestyle Products LLC  
West Palm Beach, FL  
33401  
islandcompany.com



Made in the U.S.A.

ISLAND COMPANY®



## islander<sup>®</sup> spf 6

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### colada recipe

2 FL. OZ./59ML



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Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Octinoxate 2.0%	Sunscreen
Octisalate 2.0%	
Avobenzone 2.0%	
Octocrylene 1.5%	
<b>Uses</b>	
<ul style="list-style-type: none"> <li>Helps prevent sunburn</li> <li>Higher SPF gives more sunburn protection</li> </ul>	
<b>Warnings</b>	
<ul style="list-style-type: none"> <li>For external use only</li> <li>Keep out of reach of children</li> </ul>	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>Keep out of eyes. Rinse with water to remove</li> </ul>	

<b>Stop use and ask doctor if</b>
<ul style="list-style-type: none"> <li>Rash or irritation develops and lasts</li> </ul>
<b>Directions</b>
<ul style="list-style-type: none"> <li>Apply liberally 20 minutes before sun exposure and as needed</li> <li>For children under 6 months of age: Ask a doctor</li> </ul>
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<b>Espanol</b>
Por favor agite esta botella antes de usar. Aplique de manera homogénea 20 minutos antes de exponerse al sol. Vuelva a aplicarlo después de nadar mucho tiempo, sudar copiosamente o si el producto se ha eliminado al secarse con una toalla.
<b>Francais</b>
Veillez agiter ce flacon avant l'usage. Appliquez de façon homogène 20 minutes avant d'aller au soleil. Réappliquez après une longue baignade,

une transpiration excessive, ou si vous avez enlevé le produit en vous essuyant avec une serviette.
<b>MADE IN THE U.S.A</b>
<b>distributed by:</b> Island Company Lifestyle Products LLC West Palm Beach, FL 33401 islandcompany.com

## ISLANDER SPF6

octinoxate, octisalate, avobenzone, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10755-006
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	50 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	30 mg in 1 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 g
<b>OXYBENZONE</b> (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	20 mg in 1 g
<b>OCTOCRYLENE</b> (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	15 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
ADIPIC ACID (UNII: 76A0JE0FKJ)	
DIETHYLENE GLYCOL (UNII: 61BR964293)	
GLYCERIN (UNII: PDC6A3C0OX)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ALLANTOIN (UNII: 344S277G0Z)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOL CAPPED) (UNII: T9296U138P)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10755-006-08	236 g in 1 BOTTLE		
2	NDC:10755-006-02	59 g in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/01/2009	

**Labeler** - Island Company Lifestyle Products, LLC (969086292)

## Establishment

Name	Address	ID/FEI	Business Operations
A.I.G. Technologies, Inc.		171837367	manufacture(10755-006)