PETER ISLAND CONTINOUS SUNSCREEN SPF 30- octocrylene avobenzone octisalate homosalate lotion

Access Business Group 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.

Drug Facts

Active ingredients

Avobenzone 3.0%,

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 10.0%

Purpose

Sunscreen

Warnings

For external use only

Do not use on damaged skin or broken skin

Stop use and ask a doctor

if rash occurs

When using this product

keep out of eyes. Rinse with water to remove.

keep out of reach of children

if product is swallowed, get medical help or contact a Poison Control Center right away.

• May stain some fabrics.

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 increase your risk of skin cancer and early skin aging To decrease this risk, regularly use a sunscreen with a broad spectrum SPF 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 -sleeve shirts, pants, hats and sunglasses
- children under 6 months of age:Ask a doctor

Other Information

protect this product from excessive heat and direct sun

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see directions), decrease the risk of skin cancer and early skin aging caused by the sun.

Principal Display Panel

PETER

ISLAND

Sunscreen Lotion

30

BROAD SPECTRUM

SPF 30

Moisturizing

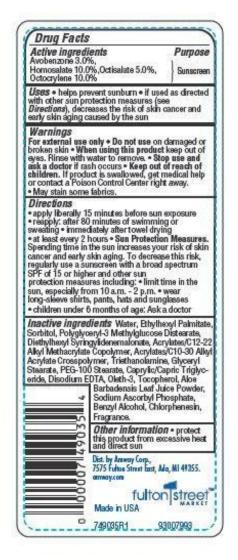
Vitamion E and Aloe

UVA/UVB Protection

Water Resistant (80 minutes)

8 FL. OZ. (236 mL)





BACK: CLEAR DIGITAL LABEL BACK COPY, SEAL & UPC: PMS 286

Inactive Ingredients

water, Ethylhexyl Palmitate, Sorbitol, Polyglyceryl-3 Methylglucoase Distearate, Diethylhexyl Syringyldenemalonate, Acrylates/C12-22 Alkyl methcrylate, Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Glyceryl Stearate, PEG_100 Stearate, Caprylic/Capric Triglyceride, Disodium EDTA, Oleth-3, Tocopherol, Aloe Barbadensis Leaf Juice Powder, Sodium

PETER ISLAND CONTINOUS SUNSCREEN SPF 30

octocrylene avobenzone octisalate homosalate lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10056-711
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g		
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	10 in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ETHYLHEXYL PALMITATE (UNII: 2865993309)		
SORBITOL (UNII: 506T60A25R)		
DIETHYLHEXYL SYRINGYLIDENEMALO NATE (UNII: 3V5U97P248)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
TROLAMINE (UNII: 903K93S3TK)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
PEG-100 STEARATE (UNII: YD01N1999R)		
TRICAPRIN (UNII: O1PB8EU98M)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
OLETH-3 (UNII: BQZ26235UC)		
TOCOPHEROL (UNII: R0ZB2556P8)		
SODIUM ASCORBYL PHOSPHATE (UNII: 836 SJG51DR)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
CHLORPHENESIN (UNII: 1670 DAL4SZ)		

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10056-711-16	226 g in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	07/09/2013		

Labeler - Access Business Group LLC (839830713)

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