

PETER ISLAND SUNSCREEN SPF 50- octocrylene oxybenzone zinc oxide lotion
ACCESS BUSINESS GROUP INTERNATIONAL 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.

Active Ingredients

Octocrylene 5.0%
Oxybenzone 2.0%
Zinc Oxide 3.9%

FOR EXTERNAL USE ONLY.

Avoid contact with eyes. Rinse with water if contact occurs.

Discontinue use if signs of rash or irritation develop.

For use on children under 6 months of age, consult a physician.

Keep out of the reach of children.

Directions

Apply generously 30 minutes prior to sun exposure. Reapply frequently and after swimming, excessive perspiration and towel drying.

This formula offers broad UVB/UVA protection from the sun's damaging rays and formulated with Zinc Oxide, a naturally sourced sunscreen. Rubs in clear and is non-greasy. Enriched with Aloe Vera and antioxidants Vitamins A, C and E. This moisturizing lotion is dermatologist tested, very water resistant, PABA-free and Fragrance free.

Inactive Ingredients

Water, Ethylhexyl Stearate, Cetyl Dimethicone, Butyloctyl Salicylate, Diisopropyl Adipate, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Beeswax, Isohexadecane, Sodium Chloride, Silica, Hydrogenated Castor Oil, Dimethicone, Disodium EDTA, PEG-8 Dimethicone, Aloe Barbadensis Leaf Juice Powder, Octyldodecanol, Retinyl Palmitate, Tocopheryl Acetate, Ascorbic Acid, Sodium Propoxyhydroxypropyl Thiosulfate Silica, Phenoxyethanol, Methylparaben, Propylparaben.

Principal Display Panel

PETER ISLAND

Sunscreen with ZINC OXIDE

SPF 50

Photostable UVB/UVA Broad Spectrum Protection

DERMATOLOGIST TESTED

Goes on Clear

4 FL OZ(118mL)

This formula offers Broad Spectrum UVB/UVA protection from the sun's damaging rays and formulated with Zinc Oxide, a naturally sourced sunscreen. Rubs in clear and is non-greasy. Enriched with Aloe Vera and antioxidants Vitamins A, C, and E. This moisturizing lotion is dermatologist tested, very water resistant, PABA-free and Fragrance free.

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INACTIVE INGREDIENTS: Water, Ethylhexyl Stearate, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Cetyl Dimethicone, Butyloctyl Salicylate, Diisopropyl Adipate, Beeswax, Isohexadecane, Dimethicone, Phenoxyethanol, Sodium Chloride, Silica, Hydrogenated Castor Oil, Methylparaben, Propylparaben, Disodium EDTA, Retinyl Palmitate, Ascorbic Acid, Tocopheryl Acetate, PEG-8 Dimethicone, Sodium Propoxyhydroxypropyl Thiosulfate Silica, Octyldodecanol, Aloe Barbadosensis Leaf Juice.

Distributed by:
Access Business Group
International LLC
7575 Fulton Street East
Ada, Michigan 49355 USA
Made in U.S.A.

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PETER ISLAND

Sunscreen
with ZINC OXIDE

spf
50

Photostable
UVB/UVA
Broad Spectrum
Protection

DERMATOLOGIST TESTED

Goes on Clear

4 FL OZ (118 mL)

PETER ISLAND SUNSCREEN SPF 50

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10056-700
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	5 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	2 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ISOHEXADECANE (UNII: 918X10UF1E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10056-700-13	113 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	11/20/2012	

Labeler - ACCESS BUSINESS GROUP INTERNATIONAL LLC (839830713)

Revised: 11/2012

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