PETER ISLAND SUNSCREENSPF 50 SPF 50- homosalate, oxybenzone, octisalate, avobenzone, octocrylene 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.

ACTIVE INGREDIENTS:

Homosalate 13.0%

Octocrylene 7.0%

Octisalate 5.0%

Oxybenzone 4.0%

Avobenzone 3.0%

WARNINGS:

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 the age of 6 months consult a physician.

Keep out of reach of children.

DIRECTIONS:

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

OTHER INFORMATION:

- May stain some fabrics
- Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

This oil tree formula provides broad spectrum UVA/UVB protection from the sun's damaging rays. It is PABA free, vitamin enriched and very water resistant.

Principal Display Panel

PETER ISLAND

Sunscreen lotion
spf 50
Photostable
Broad Spectrum
UVA/UVB Protection
Very Water Resistant
8 FL.OZ. (237 mL)


PETER
ISLAND
Sunscreen
lotion
spf
50
Photostable
Broad Spectrum
UVA/UVB Protection
Very Water Resistant
8 FL. OZ. (237 mL)

INACTIVE INGREDIENTS:

Water, Sorbitol, Stearic Acid,Triethanolamine, Aluminum Starch Octenylsuccinate, Benzyl Alcohol,Sorbitan Isostearate, VP/Eicosene Copolymer, Dimethicone, Polyglyceryl-3 Distearate, Carbomer, Tocopherol, Disodium EDTA, Methylparaben, Propylparaben, Fragrance.

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10056-702
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 g in 100 g

OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10056-702-56	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	06/27/2013	

Labeler - Access Business Group LLC (839830713)

Revised: 6/2013 Access Business Group LLC