

**PETER ISLAND BABY SUNSCREEN SPF 50- homosalate, oxybenzone, octisalate, avobenzene, 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.*

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**ACTIVE INGREDIENTS:**

Homosalate 13.0%

Octocrylene 7.0%

Octisalate 5.0%

Oxybenzone 4.0%

Avobenzene 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 formula provides Broad Spectrum UVA/UVB protection from the sun's damaging rays. It is PABA free, vitamin enriched and pediatrician tested.

## **Principal Display Panel**

PETER ISLAND

baby

Sunscreen lotion

spf 50

Pediatrician Tested

Photostable

Broad Spectrum

UVA/UVB Protection

Very Water Resistant

8 FL.OZ. (237 mL)

8 OZ BABY SPF 50

FRONT & BACK: CLEAR LABEL  
PINK BACKGROUND INDICATES BOTTLE C  
PRINT OVER WHITE WHERE POSSIBL  
DIE LINE DOES NOT PRINT



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**ACTIVE INGREDIENTS:** Homosalate 13.0%, Octocrylene 7.0%, Octisalate 5.0%, Oxybenzone 4.0%, Avobenzone 3.0%.

**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.



**Amway.**

Dist. by Amway Corp.

Ada, MI 49355.

For Questions: 1-800-253-6500

amway.com

U0006-A

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## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10056-706
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 g in 100 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 g in 100 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 g

## Inactive Ingredients

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10056-706-56	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	07/08/2013	

**Labeler** - Access Business Group LLC (839830713)