PETER ISLAND NATURAL MINERALSPF 60 SPF 60- titanium dioxide zinc oxide 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

Titanium Dioxide 2.8%

Zinc Oxide 4.0%

Purpose

Sunscreen

Warnings

For external use only.
Do not use on damaged skin or broken skin. Rinse with water to remove

When using this product keep out of eyes.

stop use and ask a doctor if rash occurs

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 literally 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 am - 2 pm
- Wear long sleeves shirts, pants, hats and sunglasses
- children under 6 month 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 caused by the sun.

Principal Display Panel

PETER

ISLAND

NATURAL MINERAL

SUNSCREEN LOTION

100%

Naturally

Sourced

Sunscreen

Ingredients

with Zinc Oxide and Titanium Dioxide

BROAD SPECTRUM

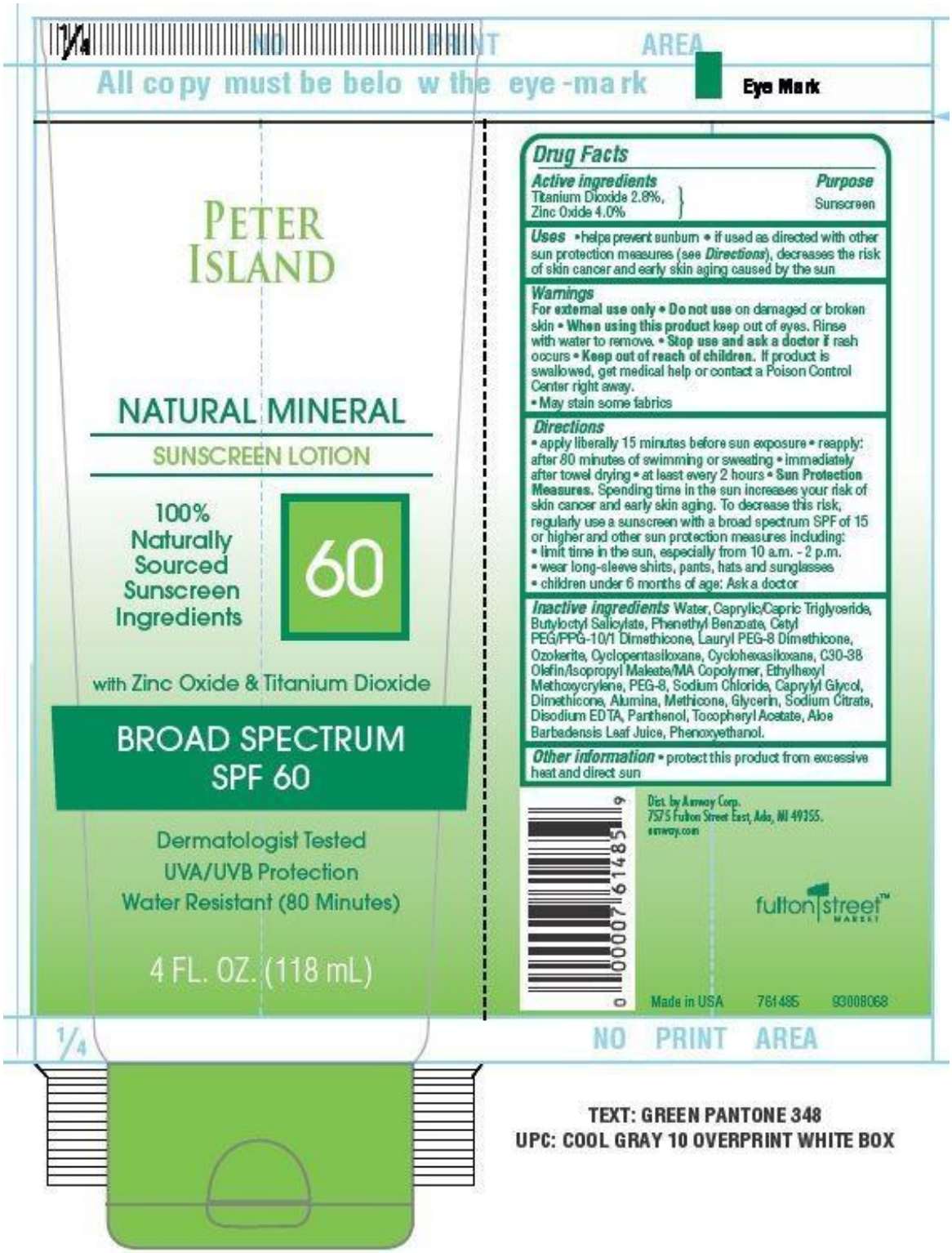
SPF 60

Dermatologist Tested

UVA/UVB Protection

Water Resistant (80 Minutes)

4 Fl. OZ. (118 mL)



INACTIVE INGREDIENTS:

Water, Caprylic Capric Triglyceride, Butyloctyl Salicylate, Phenethyl Benxoate, Cetyl PEG/PPG-10/1 Dimethicone, Laurly PEG-8 Dimethicone, Ozokerite, Cyclopentasiloxane, Cyclohexasiloxane , C30-38 Olefin/Isopropyl Maleate MA Copolymer, Ethylhexyl Methocrylene, PEG-8, Sodium Chloride, Caprylyl Glycol, Dimethicone, Alumina, Methicone, Glycerin, Sodium Citrate, Disodium EDTA, Panthenol, Tocopheryl Acetate, Aloe Barbadensis Leaf Juice, Phenoxyethanol.

PETER ISLAND NATURAL MINERALSPF 60 SPF 60

titanium dioxide zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10056-708
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.8 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
TRICAPRIN (UNII: O1PB8EU98M)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PANTHENOL (UNII: WV9CM0O67Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:10056-708-23	118 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)