

PETER ISLAND CONTINOUS SUNSCREEN SPF 50- oxybenzone, avobenzone, octocrylene spray

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%, Octocrylene 10.0%, Oxybenzone 5.0%

Purpose

Sunscreen

Warnings

For external use only

Flammable: Do not Puncture or incinerate, Contents under pressure.

Do not store at temperatures above 120 F. Do not use in the presence of a flame or spark. Keep away from sources of Ignition-No smoking.

Stop use and ask a doctor

if rash occurs

When using this product

- Keep away from face to avoid breaching it
- 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.
- Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

DIRECTIONS:

- hold container 4-6 inches from the skin to apply
- spray liberally and spread evenly by hand 15 minutes before sun exposure
- **Do not spray directly on face.**
- Spray on hands then apply to face

- do not apply in windy conditions
- use in well-ventilated area
- **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

Continuous Spray Sunscreen

Sport 50

BROAD SPECTRUM

SPF 50

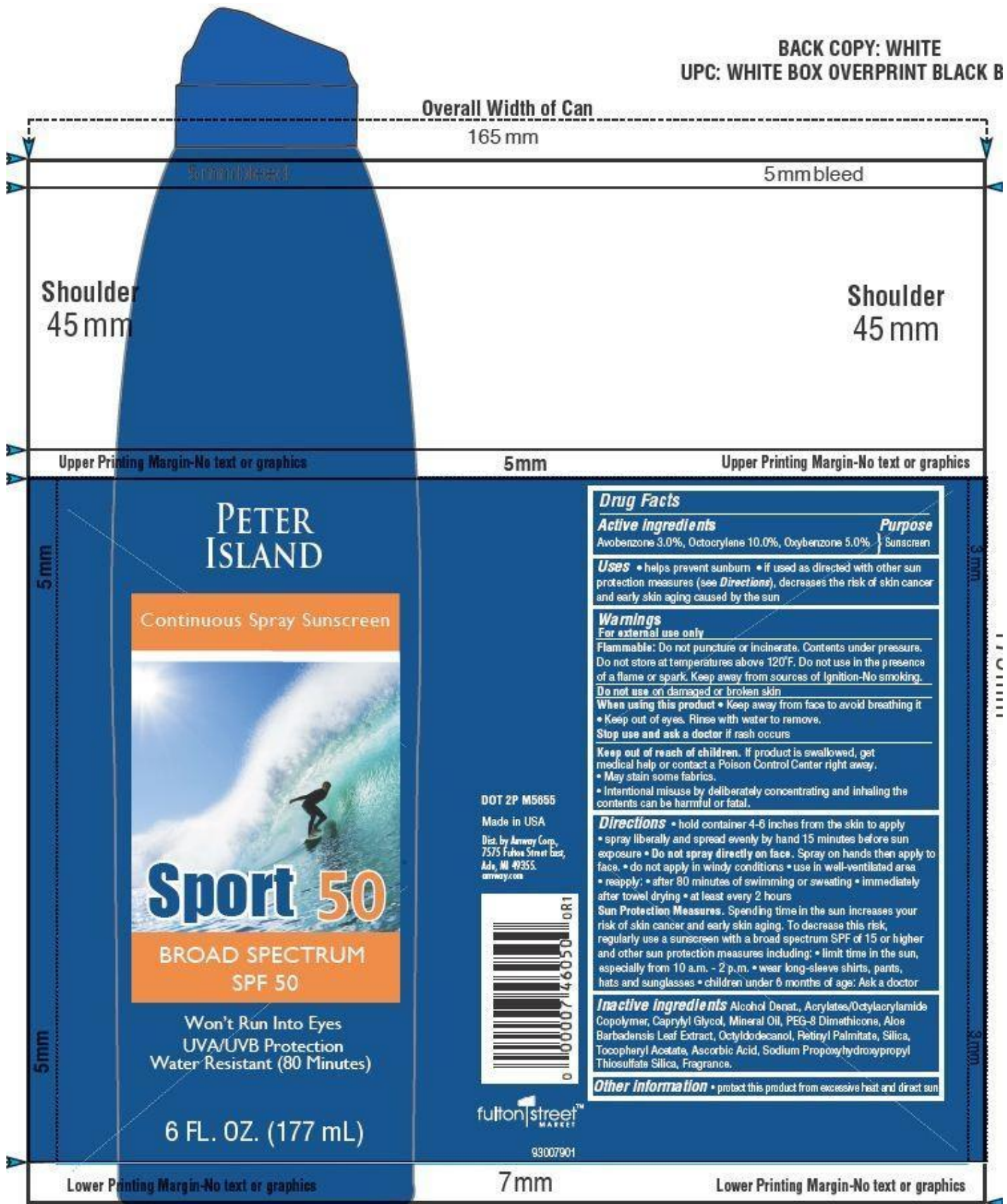
Won't Run Into Eyes

UVA/UVB Protection

Water Resistant (80 Minutes)

6 FL.OZ. (177 mL)

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Inactive Ingredients:

Alcohol decant, Acrylates/octylacrylamide Copolymer, Caprylyl Glycol, Mineral Oil, PEG_8 Dimethicone, Aloe Barbadensis Leaf Extract, Octyldodecanol, Retinyl Palmitate, Silica, Tocopheryl Leaf Extract, Ascorbic Acid, Sodium Propoxyhydroxypropyl Thiosulfate Silica, Fragrance.

PETER ISLAND CONTINOUS SUNSCREEN SPF 50

oxybenzone, avobenzone, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10056-709
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 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

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OCTYLDODECANOL (UNII: 461N10614Y)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10056-709-34	177 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)

