PUBLIX SPORT SPF 50- avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion Publix Super Markets Inc

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% Homosalate 13.0% Octisalate 5.0% Octocrylene 5.0% Oxybenzone 6.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection
- retains SPF after 80 minutes of activity in water

Warnings

For external use only

When using this product

• keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

• rash or irritation develops or lasts.

Keep out of the reach of children.

If swallowed get medical help or contact a Poison Control Center right away.

Directions

- apply generously and evenly before sun exposure and as needed
- children under 6 months of age: ask a doctor
- reapply frequently and after towel drying, swimming or perspiring

Other information

• may stain some materials

Inactive ingredients

Water, Neopentyl Glycol Diheptanoate, Styrene/Acrylates Copolymer, Propylene Glycol, Polyglyceryl-3 Methylglucose Distearate, Benzyl Alcohol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Disodium EDTA, Oleth-3, Tocopherol, Chlorphenesin, Fragrance.

Principal Display Panel

Publix sport sunscreen lotion 50 SPF VERY WATER/SWEAT RESISTANT DRY FORMULA 8 FL OZ(237 mL)



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Oxybenzone 6.0% Sunscreen

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Made in U.S.A.

PU02-A

PUBLIX SPORT SPF 50

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information	uct Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-707		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 g in 100 g		
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g		
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	5 g in 100 g		
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	6 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
TROLAMINE (UNII: 9O3K93S3TK)		
CHLORPHENESIN (UNII: 1670 DAL4SZ)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
TOCOPHEROL (UNII: R0ZB2556P8)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:56062-707-16	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	11/14/2012		

Revised: 11/2012 Publix Super Markets Inc