PUBLIX SPF 30- avobenzone, homosalate, octisalate and octocrylene 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 2.0%

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 5.0%

Purpose

Sunscreen

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 sun.

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 occurs

Keep out of the reach of children.

If 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

Inactive ingredients

Water, Ethylhexyl Plamitate, Sorbitol, Polyglyceryl-3 Methylglucose Distearate, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Glyceryl Stearate, PEG_100 Stearate, Disodium EDTA, Oleth-3, Tocopherol, Aloe Barbadensis Leaf juice Powder, Benzyl Alcohol, Chlorphenesin, Fragrance.

Principal Display Panel

publix

Ssunscreen

LOTION

BROAD SPECTRUM

SPF 15

MOISTURIZING

WATER RESISTANT

(80 MINUTES)

UVA/UVB Protection

8 FL OZ (236mL)





DASHED LINE INDICATES

PUBLIX SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:56062-709
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (AVOBENZONE)	AVOBENZONE	2 g in 100 g		
HOMOSALATE (HOMOSALATE)	HOMOSALATE	10 g in 100 g		
OCTISALATE (OCTISALATE)	OCTISALATE	5 g in 100 g		
OCTOCRYLENE (OCTOCRYLENE)	OCTOCRYLENE	5 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
WATER			
ETHYLHEXYL PALMITATE			
SORBITOL			
DIMETHICONE			
TROLAMINE			
GLYCERYL MONOSTEARATE			
EDETATE DISO DIUM			
PEG-100 STEARATE			
TOCOPHEROL			
ALOE VERA LEAF			
BENZYL ALCOHOL			
CHLORPHENESIN			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:56062-709-16	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	07/16/2013			

Labeler - Publix Super Markets Inc (006922009)

Revised: 7/2013 Publix Super Markets Inc