PUBLIX SPF 30- avobenzone, homos alate, octis alate, 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 3.0%

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 10.0%

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, Diethylhexyl Syringylidenemalonate, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Glyceryl Stearate, PEG_100 Stearate, Caprylic/Capric Triglyceride, Disodium EDTA, Oleth-3, Tocopherol, Aloe Barbadensis Leaf juice Powder, Sodium Acorbyl Phosphate, Benzyl Alcohol, Chlorphenesin, Fragrance.

Principal Display Panel

publix

SUNSCREEN

LOTION

BROAD SPECTRUM

SPF 30

MOISTURIZING

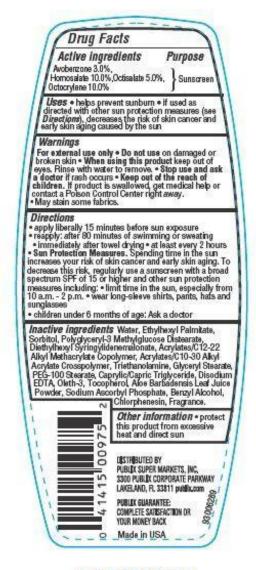
WATER RESISTINT

(80 MINTUES)

UVA/UVB Protection

8 FL OZ (236 mL)





DAQUED I INC INDICATES

publix
SUNSCREEN
LOTION
BROAD SPECTRUM
SPF 30

MOISTURIZING
WATER RESISTINT
(80 MINTUES)
UVA/UVB Protection
3 FL OZ (88 mL)



PUBLIX SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:56062-713 |
|-------------------------|----------------|--------------------|---------------|
| 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 | 10 g in 100 g | | |
| OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) | OCTISALATE | 5 g in 100 g | | |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 10 g in 100 g | | |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| WATER (UNII: 059QF0KO0R) | | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | | |
| SORBITOL (UNII: 506T60A25R) | | |
| DIETHYLHEXYL SYRINGYLIDENEMALO NATE (UNII: 3V5U97P248) | | |
| TROLAMINE (UNII: 9O3K93S3TK) | | |
| GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4) | | |
| EDETATE DISO DIUM (UNII: 7FLD9 1C86K) | | |
| PEG-100 STEARATE (UNII: YD01N1999R) | | |
| TRICAPRYLIN (UNII: 6P92858988) | | |
| OLETH-3 (UNII: BQZ26235UC) | | |
| TOCOPHEROL (UNII: R0 ZB2556 P8) | | |
| SODIUM ASCORBYL PHOSPHATE (UNII: 836 SJG51DR) | | |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) | | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | | |
| CHLORPHENESIN (UNII: 1670 DAL4SZ) | | |

| Packaging | | | | |
|--------------------|----------------------------|----------------------|--------------------|--|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 NDC:56062-713-16 | 226 g in 1 BOTTLE, PLASTIC | | | |
| 2 NDC:56062-713-22 | 85 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 | | |
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Labeler - Publix Super Markets Inc (006922009)

Revised: 7/2013 Publix Super Markets Inc