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 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 | Item Code (Source) | NDC:56062-709 | |
| Route of Administration | TOPICAL | | | |

| Active Ingredient/Active Moiety | | |
|--|-------------------|---------------|
| Ingredient Name | Basis of Strength | Strength |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 2 g in 100 g |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 10 g in 100 g |
| OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE | 5 g in 100 g |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 5 g in 100 g |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| WATER (UNII: 059QF0KO0R) | | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | | |
| SORBITOL (UNII: 506T60A25R) | | |
| DIMETHICO NE (UNII: 92RU3N3Y1O) | | |
| TROLAMINE (UNII: 9O3K93S3TK) | | |
| GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4) | | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | | |
| PEG-100 STEARATE (UNII: YD01N1999R) | | |
| TOCOPHEROL (UNII: R0ZB2556P8) | | |
| 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:56062-709-16 | 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 | | | |
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Labeler - Publix Super Markets Inc (006922009)

Revised: 7/2013 Publix Super Markets Inc