

**PUBLIX KIDS- avobenzone, homosalate, octisalate, octocrylene, oxybenzone spray**  
**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.*

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**Drug Facts**

**Active ingredients**

Avobenzone 3.0%

Homosalate 13.0%

Octisalate 5.0%

Octocrylene 2.0%

Oxybenzone 4.0%

**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, Styrene/Acrylates Copolymer, Sorbitol, Benzyl Alcohol, Triethanolamine, Dimethicone, Polyglyceryl-3 Distearate, Sorbitan Isostearate, Stearic Acid, VP/Eicosene Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tocopherol, Disodium EDTA, Methylparaben, Propylparaben, Fragrance.

## **Principal Display Panel**

Publix

kids spray sunscreen

50 SPF

MOISTURIZING

VERY WATER RESISTANT

NON-IRRITATING

Broad Spectrum Protection

8 FL OZ(237 mL)



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0 4 14 15 10 25 75 2

Drug Facts	Purpose
<b>Active ingredients</b> Avobenzone 3.0%, Homosalate 13.0%, Octisalate 5.0%, Octocrylene 2.0%, Oxybenzone 4.0%	Sunscreen
<b>Uses</b> • helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i> ), decreases the risk of skin cancer and early skin aging caused by the sun	
<b>Warnings</b> For external use only • Do not use on damaged or broken skin • 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 product is swallowed, get medical help or contact a Poison Control Center right away. • May stain some fabrics.	
<b>Directions</b> • apply liberally 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 increases 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	
<b>Inactive ingredients</b> Water, Styrene/Acrylates Copolymer, Sorbitol, Benzyl Alcohol, Triethanolamine, Dimethicone, Polyglyceryl-3 Diisostearate, Sorbitan Isoseostearate, Stearic Acid, VP/Eicosene Copolymer, Acrylates C10-30 Alkyl Acrylate Crosspolymer, Tocopherol, Disodium EDTA, Methylparaben, Propylparaben, Fragrance.	
<b>Other information</b> • protect this product from excessive heat and direct sun	

DASHED LINE INDICATES  
 PRINT AREA (1/16TH IN.  
 FROM DIELINE)

**PUBLIX KIDS**

avobenzone, homosalate, octisalate, octocrylene, oxybenzone spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:56062-706
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>SORBITAN ISO STEARATE</b> (UNII: 01S2G2C1E4)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:56062-706-16	226 g in 1 BOTTLE, PLASTIC		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352	11/14/2012	

**Labeler** - Publix Super Markets Inc (006922009)

Revised: 7/2013

Publix Super Markets Inc