# PUBLIX BABY 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.

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### **Drug Facts**

### 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

- shake well
- 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, Sorbitol, Stearic Acid, Triethanolamine, Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Sorbitan Isostearate, VP/Eicosene Copolymer, Dimethicone, Polyglyceryl-3 Distearate, Carbomer, Tocopherol, Disodium EDTA, Methylparaben, Propylparaben, Fragrance.

### **Principal Display Panel**

Publix
baby
sunscreen lotion
50
SPF
HYPOALLERGENIC
PEDIATRICIAN TESTED
VERY WATER RESISTANT
MOISTURIZING



## **Drug Facts**

## Active ingredients

Avobenzone 3.0% Homosalate 13.0% Octisalate 5.0% Octocrylene 7.0% Oxybenzone 4.0%

## Purpose

Sunscreen Sunscreen Sunscreen Sunscreen Sunscreen

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## PUBLIX BABY SPF 50

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information	Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-704		
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 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 g		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 g		
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	4 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TROLAMINE (UNII: 9O3K93S3TK)		
ALUMINUM STARCH O CTENYLSUCCINATE (UNII: 19PJ0 O 6 2 9 4)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
TOCOPHEROL (UNII: R0ZB2556P8)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:56062-704-16	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	11/15/2012		

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