SELECT BRAND BABY SUNSCREEN - avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion Select Brand Distributors

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 13.0% Octisalate 5.0% Octocrylene 7.0% Oxybenzone 4.0%

Purpose

Sunscreen

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 and lasts

Keep out of each 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

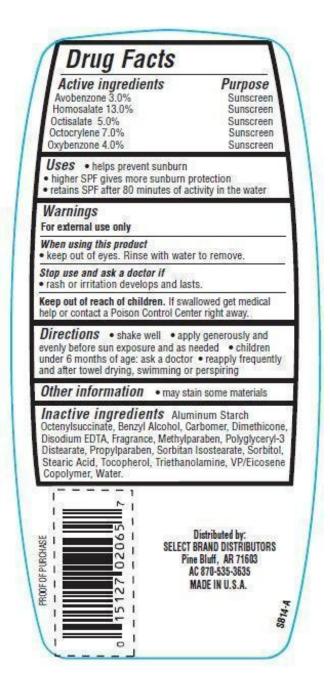
Inactive ingredients

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

select brand the lower price name brand Baby SUNSCREEN 50 SPF Very Water Resistant UVB/UVA Protection PEDIATRICIAN TESTED 8 FL OZ (237 mL)





Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection
- retains SPF after 80 minutes of activity in the water

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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15127-004	
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: 903K93S3TK)		
ALUMINUM STARCH O CTENYLSUCCINATE (UNII: 19 PJ0 O 6 29 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: 7FLD9 1C86K)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:15127-004-16	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	11/20/2012		

Labeler - Select Brand Distributors (043562370)

Revised: 11/2012 Select Brand Distributors