

AVOBENZONE, HOMOSALATE, OCTISALATE, OCTOCRYLENE- avobenzene, homosalate, octisalate, octocrylene lotion
RETAIL BUSINESS SERVICES, LLC

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.

Sunscreen for Babies SPF 50
950.000/950AA

Active ingredients

Avobenzene 3%

Homosalate 10%

Octisalate 4.5%

Octocrylene 8%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (See **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use

- on damaged or broken skin

Stop use and ask a doctor if

- rash occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- apply to all skin exposed to the sun
- 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 Broad Spectrum SPF value 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-sleeved shirts, pants, hats and sunglasses
 - children under 6 months of age: Ask a doctor

Other information

- protect the product in this container from excessive heat and direct sun

Inactive ingredients

water, glycerin, aluminum starch octenylsuccinate, styrene/acrylates copolymer, behenyl alcohol, glyceryl stearate, benzyl alcohol, PEG-100 stearate, polyester-7, tocopherol, arachidyl alcohol, acrylates/C10-30 alkyl acrylate crosspolymer, arachidyl glucoside, chlorphenesin, beeswax, silica, neopentyl glycol diheptanoate, potassium hydroxide, disodium EDTA

May stain or damage some fabrics or surfaces

Dist by Foodhold USA, LLC Landover, MD 20733 1877-846-9949

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*This product is not manufactured or distributed by Bayer, distributor of Coppertone Sunscreen Lotion Water Babies Pure & Simple Broad spectrum SPF 50

**Oxybenzone & Octinoxate free

Principal display panel

CareOne

Compare to Coppertone Sunscreen Lotion Water Babies SPF 50*

Baby Sunscreen Lotion

SPF 50 UVA/UVB protection

Broad Spectrum SPF 50

Water resistant (80 minutes)

Reef friendly

8 FL OZ (236 mL)



AVOBENZONE, HOMOSALATE, OCTISALATE, OCTOCRYLENE

avobenzene, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-950
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
DOCOSANOL (UNII: 9G1OE216XY)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYESTER-7 (UNII: 0841698D2F)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ARACHIDYL GLUCOSIDE (UNII: 6JVVW35J00J)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
neopentyl glycol diheptanoate (UNII: 5LKW3C543X)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-950-34	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/08/2019	

Labeler - RETAIL BUSINESS SERVICES, LLC (967989935)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(72476-950)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	manufacture(72476-950)

