

**AVOBENZONE, HOMOSALATE, OCTISALATE- avobenzone, homosalate, octisalate lotion
Old East Main CO.**

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 Lotion for Babies SPF 50
D47AA/D47.001**

Active ingredients

Avobenzone 3%

Homosalate 12%

Octisalate 5%

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

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 reach of children.

If swallowed, get medical help or contact a Poison Control 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, diethylhexyl 2,6-naphthalate, butyloctyl salicylate, styrene/acrylates copolymer, aluminum starch octenylsuccinate, Aloe barbadensis leaf juice, glycerin, polyester-7, silica, chlorphenesin, benzyl alcohol, arachidyl alcohol, acrylates/C10-30 alkyl acrylate crosspolymer, neopentyl glycol diheptanoate, behenyl alcohol, tocopherol, beeswax, arachidyl glucoside, potassium hydroxide, glyceryl stearate, PEG-100 stearate, disodium EDTA, sodium ascorbyl phosphate, fragrance, hexyl cinnamal, alpha-isomethyl ionone, geraniol

Disclaimer

*This product is not manufactured or distributed by Beiersdorf AG, distributor of Coppertone® Sunscreen Lotion Water Babies Broad Spectrum SPF 50.

May stain or damage some fabrics or surfaces

Adverse Reaction

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE, GOODLETTSVILLE, TN 37072

100% Satisfaction Guaranteed! (888)309-9030

Principal Panel Display

STUDIO SELECTION SUN

SUNSCREEN LOTION FOR

babies

BROAD SPECTRUM SPF 50

Compare to Coppertone® Water Babies Broad Spectrum SPF 50

- Water-Resistant (80 minutes)
- UVA/UVB Sunscreen

SPF 50

Pediatrician-Tested

Hypoallergenic

8 FL OZ (236 mL)



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75712-947
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	120 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGYM)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYESTER-7 (UNII: 0841698D2F)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
DOCOSANOL (UNII: 9G1OE216XY)	
TOCOPHEROL (UNII: R0ZB2556P8)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35J0OJ)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
GERANIOL (UNII: L837108USY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:75712-947-34	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2023	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part352		08/31/2023	

Labeler - Old East Main CO. (006946172)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon. LLC		790752542	manufacture(75712-947)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(75712-947)

Revised: 8/2023

Old East Main CO.