

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.

Sport Sunscreen Lotion SPF 50
D40.000/D40AA

Active Ingredients

Avobenzone 3%

Homosalate 12%

Octisalate 5%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protections 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 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 a 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 from excessive heat and direct sun

Inactive ingredients

water, diethylhexyl 2,6-naphthalate, butyloctyl salicylate, styrene/acrylates copolymer, aluminum starch octenylsuccinate, 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, amyl cinnamal

Disclaimer

*This product is not manufactured or distributed by Beiersdorf AG, distributor of Coppertone® Sunscreen Lotion Sport 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 display panel

STUDIO SELECTION SUN

SPORT SUNSCREEN LOTION

BROAD SPECTRUM SPF 50

Compare to Coppertone® Sport Broad Spectrum SPF 50*

SPF 50

- Water-Resistant (80 minutes)

SWEAT-RESISTANT FORMULA

8 FL OZ (236 mL)



AVOBENZONE, HOMOSALATE, OCTISALATE

avobenzone, homosalate, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75712-940
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: 059QF0K00R)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
STYRENE/ACRYLAMIDE COPOLYMER (50000 MW) (UNII: 5Z4DPO246A)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
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: 6JVW35J0OJ)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75712-940-34	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/24/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/24/2023	

Labeler - Old East Main Co. (006946172)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(75712-940)

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Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(75712-940)

Revised: 8/2023

Old East Main Co.