

**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.

**Moisturizing Sunscreen Lotion SPF 50
D54.000/D55AA**

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, neopentyl glycol diheptanoate, glyceryl stearate, silica, polyester-7, beeswax, acrylates/C10-30 alkyl acrylate crosspolymer, glycerin, potassium hydroxide, chlorphenesin, tocopherol, benzyl alcohol, arachidyl alcohol, fragrance, PEG-100 stearate, behenyl alcohol, arachidyl glucoside, disodium EDTA, amyl cinnamal, sodium ascorbyl phosphate

Adverse Reactions

May stain or damage some fabrics or surfaces

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

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

100% Satisfaction Guaranteed!

(888) 309-9030

Principal Panel Display

STUDIO SELECTION SUN

MOISTURIZING SUNSCREEN LOTION

BROAD SPECTRUM SPF 50

Compare to Coppertone® Complete Sunscreen Lotion Broad Spectrum SPF 50*

- Water-resistant (80 minutes)
- Lightweight feel

SPF 50

Dermatologist-Tested

UVA/UVB Sunscreen

3 FL OZ (89 mL)



AVOBENZONE, HOMOSALATE, OCTISALATE

avobenzone, homosalate, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75712-954
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: I0DQJ7YGXM)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYESTER-7 (UNII: 0841698D2F)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DOCOSANOL (UNII: 9G1OE216XY)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35J0OJ)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75712-954-21	89 mL in 1 TUBE; 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		790752542	manufacture(75712-954)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(75712-954)

Revised: 8/2023

Old East Main Co.