SUNSCREEN- avobenzone, homosalatem, octisalate, octocrylene 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.

Dollar General_Studio Selections 924.000/924AA

active ingredients

Avobenzone 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

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

claims

This product is not manufactured or distributed by Bayer, distributor of Coppertone Sunscreen Lotion Spectrum SPF 50

Oxybenzone & Octinoxate Free

May stain or damage some fabrics or surfaces

Distributor

DISTRIBUTED BY DOLGENCORP, LLC

100 MISSION RIDGE, GOODLETTSVILLE, TN 37072

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)

SUNSCREEN

avobenzone, homosalatem, octisalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-924
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	90 mg in 1 mL
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	1000 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	202.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	640 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYESTER-7 (UNII: 0841698D2F)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
DOCOSANOL (UNII: 9G1OE216XY)	
TOCOPHEROL (UNII: R0ZB2556P8)	
arachidyl glucoside (UNII: 6JVW35JOOJ)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-924-34	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/08/2019	

Labeler - OLD EAST MAIN CO. (068331990)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55910-924)

Revised: 6/2022

OLD EAST MAIN CO.