

**SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene spray
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.

**Care One Sunscreen Spray spf 70
983.000/983aa**

active ingredients

Avobenzone, Homosalate, Octisalate, Octocrylene

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

Flammable

Keep away from fire or flame.

- after application, wait until product dries before approaching a source of heat or flame, or before smoking

do not use

- on damaged or broken skin
- keep out of eyes. Rinse with water to remove. □ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.

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

direction

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- apply to all skin exposed to the sun
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands then apply to face.
- do not apply in windy conditions
- use in a well-ventilated area and avoid inhalation
- 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 in the container from excessive heat and direct sun

inactive ingredients

alcohol denat., octyldodecyl neopentanoate, acrylates/octylacrylamide copolymer, diethylhexyl 2,6-naphthalate, tocopheryl acetate, fragrance

May stain or damage some fabrics or surfaces

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

principal display panel

STUDIO SELECTION

SUN

BEACH GUARD

SUN & WATER

Protection

SUNSCREEN SPRAY

BROAD SPECTRUM SPF 70

Compare to Neutrogena Beach Defense Sunscreen Spray

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

SPF 70

Octinoxate & Oxybenzone Free

Dermatologist Tested

NET WT 6.5 OZ (184 g)



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-983
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzene (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	Avobenzene	90 g in 1 g
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	2250 g in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	250 g in 1 g
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	640 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-983-54	184 g in 1 CAN; Type 0: Not a Combination Product	01/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/18/2021	

Labeler - OLD EAST MAIN CO. (068331990)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55910-983)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55910-983)

Revised: 3/2022

OLD EAST MAIN CO.