

**AVOBENZONE, HOMOSALATE, OCTISALATE- avobenzone, homosalate, octisalate 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.*

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**Sport Sunscreen Spray SPF 50  
D43.000/D43AA**

**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**

**Flammable**

- 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

**When using this product**

- 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, seek immediate medical attention or call a poison control center right away.

## **Directions**

- 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 this container from excessive heat and direct sun

## **Inactive ingredients**

alcohol denat., diethylhexyl 2,6-naphthalate, diisopropyl adipate, acrylates/octylacrylamide copolymer, butyloctyl salicylate, neopentyl glycol diheptanoate, fragrance, amyl cinnamal, hydroxycitronellal, linalool, tocopheryl acetate

## **Disclaimer**

May stain or damage some fabrics or surfaces

\*This product is not manufactured or distributed by Beiersdorf AG, distributor of Coppertone® Sunscreen Spray Sport Broad Spectrum SPF 50.

## **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 SPRAY

BROAD SPECTRUM SPF 50

Compare to Coppertone® Sunscreen Spray Sport Broad Spectrum SPF 50\*

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

SPF 50

NET WT 5.5 OZ (156 g)



# AVOBENZONE, HOMOSALATE, OCTISALATE

avobenzone, homosalate, octisalate spray

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75712-943
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	120 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>DIETHYLHEXYL 2,6-NAPHTHALATE</b> (UNII: I0DQJ7YGM)	
<b>DIISOPROPYL ADIPATE</b> (UNII: P7E6YFV72X)	
<b>ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (40000 MW)</b> (UNII: 7LL6SY9YFV)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)	
<b>.ALPHA.-AMYL CINNAMALDEHYDE</b> (UNII: WC51CA3418)	
<b>HYDROXYCITRONELLAL</b> (UNII: 8SQ0VA4YUR)	
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75712-943-14	156 g in 1 CAN; Type 0: Not a Combination Product	09/29/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/29/2023	

**Labeler** - Old East Main Co. (006946172)

**Registrant** - Vi-Jon, LLC. (088520668)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC.		790752542	manufacture(75712-943)

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Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC.		088520668	manufacture(75712-943)

Revised: 9/2023

Old East Main Co.