

**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.

**Sunscreen Spray for Kids SPF 50
D42.000/D42AA**

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.

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

May stain or damage some fabrics or surfaces

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

DISTRIBUTED BY:

Old East Main Co.

100 Mission Ridge

Goodlettsville, TN 37072

*This product is not manufactured or distributed by Biersdorf AG, distributor of

Coppertone Sunscreen Spray Kids Broad Spectrum SPF 50.

May stain or damage some fabrics or surfaces

Principal display panel

Compare to Coppertone® Sunscreen Spray Kids Broad Spectrum SPF 50*

SUNSCREEN SPRAY FOR KIDS

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-442
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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 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	120 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (40000 MW) (UNII: 7LL6SY9YFV)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-442-14	156 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/11/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/25/2023	

Labeler - Old East Main Co. (068331990)

Registrant - Vi-Jon, LLC. (088520668)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC.		790752542	manufacture(55910-442)

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Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC.		088520668	manufacture(55910-442)

Revised: 8/2023

Old East Main Co.