

**SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion
DOLGENCORP, LLC**

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.

Sport Sunscreen Lotion

Active Ingredients

Avobenzone 3%

Homosalate 11.7%

Octisalate 4.5%

Octocrylene 4.5%

Oxybenzone 5.4%

Purpose

Sunscreen

Use

- 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
- 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 use 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, propylene glycol, neopentyl glycol diheptanoate, styrene/acrylates copolymer, benzyl alcohol, tocopherol, triethanolamine, acrylates/C10-30 alkyl acrylate crosspolymer, oleth-3, polyamide-8, chlorphenesin, sodium ascorbyl phosphate, fragrance, disodium EDTA

Adverse Reactions

*This product is not manufactured or distributed by Bayer, distributor of Coppertone Sport High Performance Sunscreen Broad Spectrum SPF 50.

May stain or damage some fabrics or surfaces

100% Satisfaction

Guaranteed!

(888)309-9030

DISTRIBUTED BY DOLGENCORP, LLC

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

764.000/764AA

Principal Display Panel

DG body

Compare to the

active ingredients

in Coppertone

Sport

Sunscreen Lotion

Broad Spectrum

SPF 50

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

SPF

50

8 FL OZ (237 mL)



SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-764
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.6 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	119 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	45.9 mg in 1 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	45.9 mg in 1 mL
oxybenzone (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	oxybenzone	55.08 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
OLETH-3 (UNII: BQZ26235UC)	
POLYAMIDE-8 (4500 MW) (UNII: 77723GV81A)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-764-34	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/01/2017	

Labeler - DOLGENCORP, LLC (068331990)

Registrant - Vi-Jon, Inc (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, Inc		088520668	manufacture(55910-764)