

SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion
Family Dollar Services, Inc

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
764

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

May stain or damage some fabrics or surfaces

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

Distributed by:

Family Dollar Services Inc.

10401 Monroe Rd., Matthews, NC 28105, USA

764.000/764AA

Principal Display Panel

Tropic Sun

Sport Sunscreen Lotion

Broad spectrum SPF 50

Compare to Coppertone Sport Sunscreen*

SPF 50

Water resistant (80 minutes)

UVA/UVB sunscreen

Paraben free

3 FL OZ (89 mL)



SUNSCREEN

avobenzene, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-764
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: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	45.9 mg in 1 mL

oxybenzone (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	oxybenzone	55.08 mg in 1 mL
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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:55319-764-21	89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2016	
2	NDC:55319-764-34	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/12/2016	

Labeler - Family Dollar Services, Inc (024472631)

Registrant - Vi-Jon, Inc (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, Inc		088520668	manufacture(55319-764)