SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion Moran Foods, 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 764.000/764AA

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 requiarly 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

Questions or comments?

1-800-632-6900

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

PROUDLY DISTRIBUTED BY:

VALU MERCHANDISERS, CO.

5000 KANSAS AVE

KANSAS CITY, MO 66106

764.000/764AA

principal display panel

Best Choice Sport Sunscreen Lotion

BROAD SPECTRIUM SPF 50

Compare to Coppertone UVA/UVB sunscreen

Water resistant (80 minutes)

Non-greasy

hypoallergenic

8 FL OZ (236 mL)



SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46994-764
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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45.9 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	45.9 mg in 1 mL	
oxybenzone (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	oxybenzone	55.08 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
water (UNII: 059QF0KO0R)			
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: 903K93S3TK)			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
OLETH-3 (UNII: BQZ26235UC)			
POLYAMIDE-8 (4500 MW) (UNII: 77723GV81A)			
CHLORPHENESIN (UNII: 1670DAL4SZ)			
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)			
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)			

Packaging				
# Item Code Package Description		Package Description	Marketing Start Date	Marketing End Date
1	NDC:46994- 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 - Moran Foods, LLC (095484572)

Registrant - Vi-Jon, LLC (790752542)

Establishment					
Name	Address	ID/FEI	Business Operations		
Vi-Jon, LLC		088520668	manufacture(46994-764)		

Revised: 9/2023 Moran Foods, LLC