SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene 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 714.000/714AA

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 10%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protections measures (see Directions), decreases the rist 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, 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 u 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, ethylhexyl palmitate, sorbitol, polyamide-8, benzyl alcohol, tocopherol, caprylic/capric triglyceride, triethanolamine, fragrance, acrylates/C10-30 alkyl acrylate crosspolymer, chlorphenesin, sodium ascorbyl phosphate, oleth-3, disodium EDTA

Questions or comments?

1-800-632-6900

*This product is not manufactured or distributed by Bayer, Distributor of Coppertone Sport High Performance Broad Spectrum SPF 30

PROUDLY DISTRIBUTED BY:

VALU MERCHANDISERS, CO.

5000 KANSAS AVE

KANSAS CITY, MO 66106

May stain or damage some fabrics or surfaces.

714.000/714AA

principal display panel

Best Choice Sport Sunscreen Lotion

Broad Spectrum SPF 30

Compare to Coppertone

UVA/UVB sunscreen

Water resisitant (80 minutes) Non-greasy

Hypoallergenic

8 FL OZ (236 mL)



SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46994-714
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.3 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	101 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50.5 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	101 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
water (UNII: 059QF0KO0R)		
ETHYLHEXYL PALMITATE (UNII: 2865993309)		
SORBITOL (UNII: 506T60A25R)		
POLYAMIDE-8 (4500 MW) (UNII: 77723GV81A)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
TOCOPHEROL (UNII: ROZB2556P8)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
TROLAMINE (UNII: 903K93S3TK)		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)		
CHLORPHENESIN (UNII: 1670DAL4SZ)		
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)		
OLETH-3 (UNII: BQZ26235UC)		
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)		

l	Packaging				
	#	# Item Code Package Description		Marketing Start Date	Marketing End Date
		NDC:46994- 714-34	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/28/2016	

Marketing Information				
Marketing Application Number or Monograp Category Citation		Marketing Start Date	Marketing End Date	
OTC monograph final	part352	11/28/2016		

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		088520668	manufacture(46994-714)	

Revised: 9/2023 Moran Foods, LLC