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.

Sunscreen Lotion 769

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, olethe-3, disodium EDTA

Questions or comments?

1-800-632-6900

*This product is not manufacured or distribued by Bayer, distributor of Coppertone Ultra Guard Sunscreen Lotion Broad Spectrum SPF 30.

May stain or damage some fabrics or surfaces.

PROUDLY DISTRIBUTED BY:

VALU MERCHANDISERS, CO.

5000 KANSAS AVE

KANSAS CITY, MO 66106

769.000/769AA

principal display panel

compare to Coppertone*

Best Choice Sunscreen Lotion

BROAD SPECTRUM SPF 30

water resistant (80 minutes)



SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46994-769
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	30.3 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: R0ZB2556P8)		
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
l	1	NDC:46994- 769-34	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(46994-769)

Revised: 9/2023 Moran Foods, LLC