SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene lotion
American Sales Company

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.

Ultra Sunscreen Lotion SPF 50
940.000/940AA

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 4.5%

Octocrylene 8%

Purpose

Sunscreen

Use

- 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 {and evenly} 15 minutes before sun exposure
■ apply to all skin exposed to the sun
■ 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 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, glycerin, aluminum starch octenylsuccinate, styrene/acrylates copolymer, polyester-7, silica, chlorphenesin, arachidyl alcohol, beeswax, neopentyl glycol diheptanoate, acrylates/C10-30 alkyl acrylate crosspolymer, behenyl alcohol, tocopherol, arachidyl glucoside, glyceryl stearate, PEG-100 stearate, potassium hydroxide, fragrance, benzyl alcohol, disodium EDTA

May stain or damage some fabrics or surfaces

Dist by Foolhold USA, LLC

Landover, MD 20785 1-877-848-8949

(c) S&S Brands, LLC

Quality guraranteed or your money back.

*This product is not manufactured or distributed by Bayer, distributor of Coppertone Ultra Guard Sunscreen Lotion Broad Spectrum SPF 50.

*Oxybenzone & Octinoxate Free

Principal Panel Display

Care One

Compare to Coppertone sunscreen Lotion Ultra Guard SPF 50*

SUNSCREEN LOTION

SPF 50 UVA/UVB protection

BROAD SPECTRUM SPF 50

Water-Resistand (80 minutes)

- Enriched with moisturizers
- Hypoallergenic
- Reef friendly

8 FL OZ (236 mL)

SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-940
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
POLYESTER-7 (UNII: 0841698D2F)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
neopentyl glycol diheptanoate (UNII: 5LKW3C543X)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
DOCOSANOL (UNII: 9G1OE216XY)	
tocopherol (UNII: R0ZB2556P8)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-940-34	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/08/2019	

Labeler - American Sales Company (809183973)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(41520-940)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(41520-940)

Revised: 4/2023

American Sales Company