# AVOBENZONE, HOMOSALATE, OCTISALATE- avobenzone, homosalate, octisalate lotion Meijer Distribution

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.

-----

## Moisturizing Sunscreen Lotion SPF 50 D54.000/D54AA

#### **Active Ingredients**

Avobenzone 3%

Homosalate 12%

Octisalate 5%

#### **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
- 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, diethylhexyl 2,6-naphthalate, butyloctyl salicylate, styrene/acrylates copolymer, aluminum starch octenylsuccinate, neopentyl glycol diheptanoate, glyceryl stearate, silica, polyester-7, beeswax, acrylates/C10-30 alkyl acrylate crosspolymer, glycerin, potassium hydroxide, chlorphenesin, tocopherol, benzyl alcohol, arachidyl alcohol, fragrance, PEG-100 stearate, behenyl alcohol, arachidyl glucoside, disodium EDTA, amyl cinnamal, sodium ascorbyl phosphate

May stain or damage some fabrics or surfaces

\*This product is not manufactured or distributed by Beiersdorf AG, distributor of Coppertone® Complete Sunscreen Lotion SPF 50.

#### Adverse Reaction

Our Quality Guraranteed

The Meijer Family

WWW.MEIJER.COM/SATISFACTION

Questions 1-888-593-0593

**DISTRIBUTED BY** 

MEIJER DISTRIBUTION, INC.

GRAND RAPIDS, MI 49544

www.meijer.com

### **Principal Panel Display**

meijer

moisturizing sunscreen lotion

**BROAD SPECTRUM SPF 50** 

**UVA/UVB SUNSCREEN** 

SPF 50

WATER RESISTANT (80 MINUTES)

**DERMATOLOGIST TESTED** 

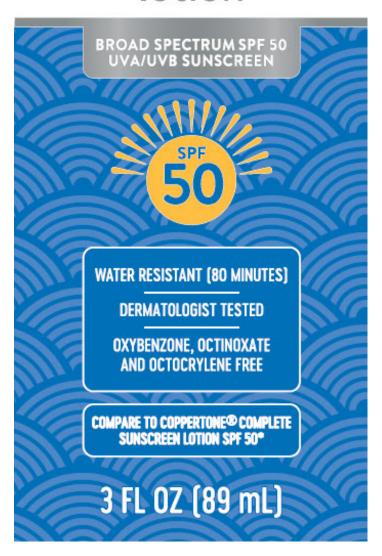
OXYBENZONE, OCTINOXATE AND OCTOCRYLENE FREE

COMPARE TO COPPERTONE® COMPLETE SUNSCREEN LOTION SPF 50\*

3 FL OZ (89 mL)

## meijer.

## moisturizing sunscreen lotion



## **AVOBENZONE, HOMOSALATE, OCTISALATE**

avobenzone, homosalate, octisalate lotion

e) NDC:79481-0954

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	

AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	120 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
STYRENE (UNII: 44LJ2U959V)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ 1374NL9E)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ0O6294)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYESTER-7 (UNII: 0841698D2F)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
.ALPHAAMYLCINNAMALDEHYDE (UNII: WC51CA3418)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	

Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date
1	NDC:79481- 0954-1	89 mL in 1 TUBE; Type 0: Not a Combination Product	08/28/2023	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/28/2023	

## **Labeler -** Meijer Distribution (006959555)

## Registrant - Vi-Jon, LLC (790752542)

Establishment					
Name	Address	ID/FEI	Business Operations		
Vi-Jon, LLC		790752542	manufacture(79481-0954)		

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Vi-Jon, LLC		088520668	manufacture(79481-0954)	

Revised: 8/2023 Meijer Distribution