SUNSCREEN- avobenzone, homosalate, octisalat, octocrylene lotion Retail Business Services, 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.

Care One 922.000/922AA

Active ingredient

Avobenzone Homosalate Octisalate Octocrylene

Purpose

sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer

Warnings

For external use only

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 minute of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- Sun Protection Measures. Spending time in the sun increases your rist of skin

cancer and early skin aging. To decrease this risk, regularly use a sunscreen with 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
- childre under 6 months of age: ask a doctor

Other information

protect the product in this container from excessive heat and dirtect sun

Inactive ingredients

water, diethylhexyl 2,6-naphthalate, styrene/acrylates copolymer, silica, glyceryl stearate, PEG-100 stearate, beeswax, cyclopentasiloxane, acrylates/dimethicone copolymer, acrylates/C10-30 alkyl acrylate crosspolymer, fragrance, chlorphenesin, benzyl alcohol, triethanolamine, disodium EDTA, BHT

May stain or damage some fabrics or surfaces

This product is not manufactured or distributed by Johnson & Johnson Consumer, Inc., distributor of Neutrogena Ultra Sheer Dry-Touch Sunscreen Broad Spectrum SPF 100+

DISTRIBUTED BY: ADUSA DISTRIBUTION. LLC

SALISBURY, NC 28147

1-833-992-3872

Quality guaranteed or your money back.

principal display panel

CAREONE

Compare to Neutrogena Ultra Sheer Sunscreen Broad Spectrum SPF 100+

SHEET TOUCH

Sunscreen Lotion

SPF 100

UVA/UVB PROTECTION

Broad Spectrum SPF 100

- Water resistant (80 min)
- Clean and lightweight feel
- Quickly absorbs
- Oxybenzone & Octinoxate Free Formula

NET 3 FL OZ (88 mL)



SUNSCREEN

avobenzone, homosalate, octisalat, octocrylene lotion

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:72476-117 Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	90 mg in 1 mL		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	2250 mg in 1 mL		
Octisalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	250 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1000 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: IODQJ7YGXM)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
benzyl alcohol (UNII: LKG8494WBH)	
TROLAMINE (UNII: 903K93S3TK)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

l	Packaging				
	#	Item Code	Item Code Package Description		Marketing End Date
		NDC:72476-117- 21	88 mL in 1 TUBE; Type 0: Not a Combination Product	11/30/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/30/2021	

Labeler - Retail Business Services, LLC (967989935)

Registrant - Vi-Jon, LLC (088520668)

Establishme	nt		
Name	Address	ID/FEI	Business Operations

Vi-Jor	n, LLC	088520668	manufacture(72476-117)	
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Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72476-117)

Revised: 2/2022 Retail Business Services, LLC