

**SUNSCREEN- avobenzone, homosalate, otisalate, octocrylene spray  
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.*

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**Sheer Touch Sunscreen SPF 70  
978.000/978AA**

**active ingredients**

Avobenzone 3%

Homosalate 15%

Octisalate 5%

Octocrylene 10%

**Purpose**

Sunscreen

**uses**

- helps prevent sunburn
- if used as directed with other skin protection measures (see **Directions**), decreases the risk 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 in the container from excessive heat and direct sun

### **inactive ingredients**

water, styrene/acrylates copolymer, silica, diethylhexyl 2,6-naphthalate, beeswax, glyceryl stearate, PEG-100 stearate, glycerin, caprylyl methicone, cetyl dimethicone, sodium polyacrylate, acrylates/C12-22 alkyl methacrylate copolymer, dimethicone, xanthan gum, pentylene glycol, trimethylsiloxysilicate, disodium EDTA, fragrance, BHT, benzyl alcohol, chlorphenesin

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Neutrogena Ultra Sheer Dry-Touch Sunscreen Broad Spectrum SPF 70.

MAY STAIN OR DAMAGE SOME FABRICS OR SURFACES.

Distributed by: ADUSA Distribution, LLC

Salisbury, NC 28147

1-833-922-3872

Quality Guaranteed or your money back.

### **Principal Display Panel**

CAREONE

Compare to Neutrogena Ultra Sheer Dry Touch Sunscreen Broad Spectrum SPF 70\*

Sheer Touch Sunscreen Lotion

SPF 70 UVA/UVB Protection

Water resistant (80 mins)

Clean & lightweight feel

Quickly absorbs

Formulated without Oxybenzone & Octinoxate

NET 3 FL OZ (88 mL)



## SUNSCREEN

avobenzene, homosalate, otisalate, octocrylene spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-978
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	150 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>styrene</b> (UNII: 44LJ2U959V)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>DIETHYLHEXYL 2,6-NAPHTHALATE</b> (UNII: I0DQJ7YGYM)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 stearate</b> (UNII: YD01N1999R)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>CETYL DIMETHICONE 150</b> (UNII: 5L694Y0T22)	
<b>SODIUM POLYACRYLATE (2500000 MW)</b> (UNII: 05I15JN12J)	
<b>BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER</b> (UNII: 7K68DGG29P)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>pentylene glycol</b> (UNII: 50C1307PZG)	
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-978-21	88 mL in 1 TUBE; Type 0: Not a Combination Product	01/05/2023	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/05/2023	

**Labeler** - RETAIL BUSINESS SERVICES , LLC (967989935)

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Vi-Jon, LLC		790752542	manufacture(72476-978)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Vi-Jon, LLC		088520668	manufacture(72476-978)

Revised: 1/2023

RETAIL BUSINESS SERVICES , LLC