SUNSCREEN- sunscreen 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.

Moisturizing Sunscreen Lotion SPF 50
D50AA/D50.000

Active ingredients

Avobenzone 3%

Homosalate 12%

Octisalate 5%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun 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 liberaly 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 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 this container from excessive heat and direct sun

Inactive ingredients

water, diethylhexyl 2,6-naphthalate, butyloctyl salicylate, styrene/acrylates copolymer, aluminum starch octenylsuccinate, glycerin, 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, benzyl alcohol, disodium EDTA, sodium ascorbyl phosphate, fragrance

May stain or damage some fabrics or surfaces

DISTRIBUTED BY:

ADUSA DISTRIBUTION, LLC

SALISBURY, NC 28147

For product questions or concerns, contact us at 1-833-992-3872

Quality guaranteed or your money back.

principal display panel

CAREONE®

Broad Spectrum

SUNSCREEN LOTION

SPF 50

UVA/UVB SUNSCREEN

Broad Spectrum SPF 50

Contains Vitamin E

Dermatologist tested

Hypoallergenic

Water resistant (80 minutes)

Oxybenzone + Octinoxate Free

6 FL OZ (177 mL)

SUNSCREEN

sunscreen lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72476-951
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	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)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYESTER-7 (UNII: 0841698D2F)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S) (UNII: 8Z5ZAL5H3V)	
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)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-951-30	177 mL in 1 TUBE; Type 0: Not a Combination Product	09/29/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/29/2023	

Labeler - RETAIL BUSINESS SERVICES , LLC (967989935)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72476-951)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(72476-951)

Revised: 9/2022 RETAIL BUSINESS SERVICES , LLC