

AVOBENZONE, HOMOSALATE, OCTISALATE- avobenzone, homosalate, octisalate lotion
Old East Main Co.

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.

Sheer Touch Sunscreen SPF 100
D34.000/D34AA

Active Ingredients

Avobenzone 3%

Homosalate 15%

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 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 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, styrene/acrylates copolymer, butyloctyl salicylate, silica, glyceryl stearate, PEG-100 stearate, potassium cetyl phosphate, beeswax, behenyl alcohol, acrylates/C12-22 alkyl methacrylate copolymer, benzyl alcohol, fragrance, xanthan gum, chlorphenesin, sodium polyacrylate, glycerin, disodium EDTA, BHT, trideceth-6, pentylene glycol

Adverse Reaction

May stain or damage some fabrics or surfaces.

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE,

GOODLETTSVILLA, TN 37072

100% Satisfaction Guaranteed!

(888) 309-9030

Principal display panel

STUDIO SELECTION SUN

SHEER TOUCH SUNSCREEN LOTION

BROAD SPECTRUM SPF 100

UVA/UVB SUNSCREEN

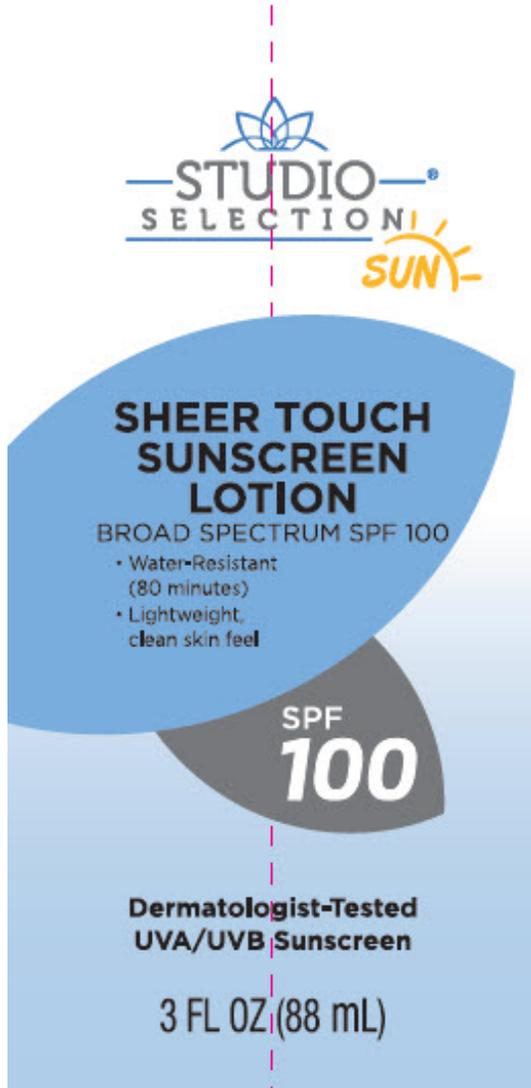
SPF 100

- WATER RESISTANT (80 MINUTES)
- LIGHTWEIGHT, clean skin feel

Dermatologist-Tested

UVA/UVB Sunscreen

3 FL OZ (88 mL)



AVOBENZONE, HOMOSALATE, OCTISALATE

avobenzone, homosalate, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75712-934
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	150 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)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
DOCOSANOL (UNII: 9G10E216XY)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75712-934-21	88 mL in 1 TUBE; Type 0: Not a Combination Product	08/25/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/25/2023	

Labeler - Old East Main Co. (006946172)

Registrant - Vi-Jon, LLC (088520668)

Establishment

Name	Address	ID/FEI	Business Operations
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Vi-Jon, LLC		790752542	manufacture(75712-934)
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Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(75712-934)

Revised: 8/2023

Old East Main Co.