

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

Studio Selection D34.000/D34AA
Sheer Touch Sunscreen SPF 100

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,

GOODLETTSVILLE, TN 37072

100% Satisfaction Guaranteed!

(888) 309-9030

OCTINOXATE FREE

OXYBENZONE FREE

Principal display panel

STUDIO SELECTION™

SUN

SHEER TOUCH SUNSCREEN LOTION

BROAD SPECTRUM SPF 100

- WATER RESISTANT (80 MINUTES)

- LIGHTWEIGHT, clean skin feel

SPF 100

Dermatologist-Tested

UVA/UVB Sunscreen

3 FL OZ (88 mL)



Drug Facts

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Avobenzone 3%	Sunscreen
Homosalate 14%	Sunscreen
Octisalate 5%	Sunscreen

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Other information
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Inactive ingredients water, diethylhexyl 2-o-sultholate, 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, carboxyl gum, chloropheniramine, sodium polyacrylate, glycerin, dipotassium EDTA, BHT, bis(2-ethyl-6-tert-butyl-4-methylphenyl)glycol

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 GOODLETTSVILLE, TN 37072

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OCTINOXATE FREE
 OXYBENZONONE FREE
 L00212601A

May stain or damage some fabrics or surfaces

B0494
 0 72785 14491 0

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: 059QF0K00R)	
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: 9G1OE216XY)	
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 Drug	M020	08/25/2023	

Labeler - Old East Main Co. (006946172)

Registrant - Nice-Pak Products, LLC (119091520)

Establishment

Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(75712-934)

