AVOBENZONE, HOMOSALATE, OCTISALATE- avobenzone, homosalate, octisalate spray 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 Mist SPF 100 D36.000/D36AA

Active ingreidnets

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

Flammable: Keep away from fire or flame.

 after application, wait until product dries before approaching a source of heat or flame, or before smoking

Do not use

• on damaged or broken skin

When using this product

- keep out of eyes. Rinse with water to remove.
- contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.

Stop use and ask a doctor if

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- apply to all skin exposed to the sun
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands then apply to face.
- do not apply in windy conditions
- use in a well-ventilated area and avoid inhalation
- 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 this container from excessive heat and direct sun

Inactive ingredients

alcohol denat., diisopropyl adipate, diethylhexyl 2,6-naphthalate, butyloctyl salicylate, neopentyl glycol diheptanoate, acrylates/octylacrylamide copolymer, fragrance, benzyl benzoate, butylphenyl methylpropional, citronellol, tocopheryl acetate

Adverse events

May stain or damage some fabrics or surfaces

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Principal Panel Display

STUDIO SELECTION SUN

SHEER TOUCH

SUNSCREEN MIST

BROAD SPECTRUM SPF 100

- Water-Resistant (80 minutes)
- Absorbs quickly

SPF 100

UVA/UVB Sunscreen

NET WT 5.5 OZ (156 g)



AVOBENZONE, HOMOSALATE, OCTISALATE

avobenzone, homosalate, octisalate spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-936	
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 g	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	150 mg in 1 g	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)		
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)		
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)		
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)		
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)		
BENZYL BENZOATE (UNII: N863NB338G)		
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)		
.BETACITRONELLOL, (R)- (UNII: P010UT964K)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		

I	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:55910-936-	156 g in 1 CAN; Type 0: Not a Combination Product	06/29/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/29/2023	

Labeler - Old East Main Co. (068331990)

Registrant - Vi-Jon, LLC (088520668)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55910-936)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55910-936)

Revised: 6/2023 Old East Main Co.