

**SUNSCREEN- octinoxate, octisalate, zinc oxide cream
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.

Dollar General Studio Selection 726

claims

CLEAR ZINC SUNSCREEN

BROAD SPECTRUM SPF 50

Dermatologist-Tested • UVA/UVB Protection
Goes on Clear • With Aloe and Vitamin E

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

Directions

- apply liberally 15 minutes before sun exposure
- 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 from excessive heat and direct sun

inactive ingredients

water, butyloctyl salicylate, C12-15 alkyl benzoate, caprylic/capric triglyceride, glyceryl stearate, propanediol, triacontanyl PVP, cetearyl alcohol, PEG-100 stearate, cetearyl glucoside, glyceryl behenate, dimethicone, glycerin, PEG-150/decyl alcohol/SMDI copolymer, Aloe barbadensis leaf juice, allantoin, panthenol, tocopheryl acetate, triethoxycaprylylsilane, fragrance, phenoxyethanol, methylisothiazolinone, tetrasodium EDTA

claims

May stain or damage some fabrics or surfaces

disclaimer

This product is not manufactured or distributed by Bayer, distributor of Coppertone Sunscreen Spray Sport Broad Spectrum SPF 70

DSP-TN-15000 DSP-MO-34 SDS-TN-15012

100%

Satisfaction

Guaranteed!

(888)309-9030

Adversation reaction

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

Principal Display Panel

STUDIO

SELECTION SUN

CLEAR ZINC SUNSCREEN

BROAD SPECTRUM SPF 50

- Water-Resistant (80 minutes)
- For face, nose or ears
- Paraben Free

SPF 50

NET WT 1 OZ (28.3 g)



SUNSCREEN

octinoxate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-726
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	562 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	250 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1000 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1000 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPANEDIOL (UNII: 5965N8W85T)	
TRICONTANYL POVIDONE (UNII: N0SS3Q238D)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-150/DECYL ALCOHOL/SMDI COPOLYMER (1350 MPA.S AT 3%) (UNII: VP5LS3541F)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALLANTOIN (UNII: 344S277G0Z)	
PANTHENOL (UNII: WW9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
EDETATE SODIUM (UNII: MP1J8420LU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-726-10	28.3 g in 1 PACKAGE; Type 0: Not a Combination Product	10/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/01/2019	

Labeler - OLD EAST MAIN CO. (068331990)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55910-726)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55910-726)

Revised: 3/2022

OLD EAST MAIN CO.