

DERMISA SUNSCREEN SPF 55 BROAD SPECTRUM- octinoxate, titanium dioxide, zinc oxide lotion

Montani Cosmetics Inc

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.

Drug Facts

Active Ingredients

Avobenzone 3.00%

Homosalate 10.00%

Octisalate 5.00%

Octocrylene 2.75%

Oxybenzone 6.00%

Purpose

Sunscreen

Sunscreen

Sunscreen

Sunscreen

Sunscreen

Uses

helps prevent sunburn

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

Directions

- apply 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 of 15 or higher and other sun protection measures including: • limit time in sun, especially from 10 a.m.- 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a Doctor

Other information

- protect this product from excessive heat and direct sun • might stain fabrics • store at room temperature

Inactive Ingredients

Behenyl Alcohol, BHT, Butyloctyl Salicylate, Caprylyl Methicone, Dimethicone, Dimethyl Capramide, Disodium EDTA, Ethylhexyl Stearate, Ethylhexylglycerin, Ethylparaben, Fragrance, Glyceryl Stearate, Iodopropynyl Butylcarbamate, Methylparaben, PEG-100 Stearate, Phenoxyethanol, Polyester-8, Propylparaben, Silica, Sodium Polyacrylate, Styrene/Acrylates Copolymer, Trideceth-6, Trimethylsiloxysilicate, VP/Hexadecene Copolymer, Water, Xanthan Gum

Package Label

NEW



SUNSCREEN LOTION

BROAD SPECTRUM SPF 55

Lightweight lotion
UVA/UBV protection
dermatologist tested



WATER RESISTANT
(80 MINUTES)

4 FL OZ (118 mL)

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DERMISA SUNSCREEN SPF 55 BROAD SPECTRUM

octinoxate, titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68343-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.75 g in 100 mL

AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
WATER (UNII: 059QF0KO0R)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DOCOSANOL (UNII: 9G1OE216XY)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68343-003-04	118 mL in 1 TUBE; Type 0: Not a Combination Product	09/08/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/08/2017	

Labeler - Montani Cosmetics Inc (124852331)