MIMOSA LANE SPF45- octinoxate, octisalate, zinc oxide sunscreen cream R&G Divergency LLC

Mimosa Lane SPF45

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 physician if rash occurs. If product is swallowed get medical help or contact a Poison Control Center right away.

Active Ingredients

Octinoxate 7.5% Octisalate 3.0% Zinc Oxide 8.0%

Indications and Usage

Helps prevent sunburn. If used as directed with other sun protection measure (See Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Purpose

Sunscreen

Keep out of reach of children

Keep out of reach of children

Directions

Apply liberally 15 minutes before sun exposure. Reapply: after 80 minutes of swimming or sweating, immediately after towel drying and 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 the sun, especially from 10 am to 2 pm. Wear long-sleeve shirts, pants, hats, and sunglasses. Children under 6 months: ask a physician.

Other information

Protect this product from excessive heat and direct sun.

Inactive Ingredients

water, cyclopentasiloxane, ethylhexyl isononanoate, butylene glycol, lauryl PEG-9 polydimethylsiloxyethyl dimethicone, dimethicone, phenoxyethanol, sodium chloride, triethoxycaprylylsilane, dimethicone/PEF-10/15 crosspolymer, dimethicone/vinyl dimethicone crosspolymer, sodium hyaluronate, iodopropynyl butylcarbamate, ascorbyl palmitate, retinyl palmitate, tocopherol

Questions

Call toll free 1-844-940-2918 Email: contact@mimosalane.com

Labeling





MIMOSA LANE SPF45

octinoxate, octisalate, zinc oxide sunscreen cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84554-0006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 g in 1000 g		
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	30 g in 1000 g		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	80 g in 1000 g		

Inactive Ingredients			
Ingredient Name	Strength		
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)			
WATER (UNII: 059QF0KO0R)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
HYALURONIC ACID (UNII: S270N0TRQY)			

CYCLOMETHICONE (UNII: NMQ347994Z)

ASCORBYL PALMITATE (UNII: QN83US2B0N)

VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)

DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)

DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)

LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)

ETHYLHEXYL ISONONANOATE (UNII: 16KB4GE3K4)

TOCOPHEROL (UNII: ROZB2556P8)

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:84554- 0006-1	150 g in 1 TUBE; Type 0: Not a Combination Product	08/30/2024		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	08/30/2024		

Labeler - R&G Divergency LLC (064143971)

Registrant - Swiss-American CDMO, LLC (080170933)

Establishment					
Name	Address	ID/FEI	Business Operations		
Swiss-American CDMO, LLC		080170933	manufacture(84554-0006)		

Revised: 8/2024 R&G Divergency LLC