ALDANA SKIN LIFE - SUNSCREEN BROAD SPECTRUM SPF 55 WATER RESISTANT (80 MINS.)- octinoxate and zinc oxide lotion Cosmetic Solutions LLC

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.

Aldana Skin Life - Sunscreen Broad Spectrum SPF 55 Water Resistant (80 Mins.)

DRUG FACTS:

ACTIVE INGREDIENTS

Octinoxate 7.5%, Zinc Oxide 4.8%

PURPOSE

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 liberally and evenly 15 minutes before sun exposure. ¹Reapply: At least 80 minutes after 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 the sun, especially from 10 a.m. 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses.

INACTIVE INGREDIENTS

¹ For children under 6 months of age: Ask a doctor.

Water, Hydrogenated Polybutene, Octyl Stearate, Polyglyceryl-4-Isostearate, Aloe Barbadensis Leaf Extract, Isopropyl Palmitate, Cyclomethicone, Sunflower Oil, Hydrogenated Microcrystalline Wax, Cetyl Dimethicone Copolyol, Cetyl Dimethicone, Hydrogenated Castor Oil, Sodium Chloride, Polyglyceryl-3-Oleate, Silica, Hexyl Laurate, Triethoxycaprylylsilane, Capryly Glycol, Methylisothiazolinone.

OTHER INFORMATION

Protect the product in this container from excessive heat and direct sun.

PRINCIPAL DISPLAY PANEL - 60 G Bottle Label

ALDANA SKIN LIFE

uv PROTECTIVE

SUNSCREEN

BROAD SPECTRUM SPF 55

WATER RESISTANT (80 MINS.)

60 G (NET WT. 2 OZ)









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MANUFACTURED FOR ALDANA SKIN LIFE Doral, Florida 33178 | LB48788A

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octinoxate and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66163-5500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	48 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
OCTYL STEARATE (UNII: 772Y4UFC8B)		
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)		
CYCLOMETHICONE (UNII: NMQ347994Z)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
POLYGLYCERYL-3 OLEATE (UNII: XRQ165498B)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
HEXYL LAURATE (UNII: 4CG9F9W01Q)		
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66163- 5500-1	60 g in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2022	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	05/01/2022		

Labeler - Cosmetic Solutions LLC (807907928)

Revised: 4/2022 Cosmetic Solutions LLC