

MAUI NATURALS ALL NATURAL SUNSCREEN- zinc oxide lotion
Hawaiian Classic Perfumes, 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.

Hawaiian Classic Perfumes OTC Private Label Sunscreen - Maui Naturals All Natural Sunscreen

Maui Naturals All Natural Sunscreen Lotion SPF 30



(Front Label:)

Broad Spectrum - Maui Naturals - All Natural Sunscreen SPF 30 - Eco/Reef Friendly - no avo/oxybenzones - no petrochemicals - no nano particles - water resistant - 80 Min - with Maui Grown Essential Oils - 3 ounces /90 mL



(Back Label:)

Drug Facts

Active Ingredient – Purpose

Zinc Oxide (20%)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. 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 15 minutes before sun exposure

*re-apply:

*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 a.m. - 2 p.m.

*wear long-sleeve shirts, pants, hats, and sunglasses

*children under 6 months: Ask a doctor.

Inactive Ingredients: Aloe Barbadosensis Leaf Juice, Capric Caprylic Triglycerides, Castor Oil, Hydrogenated Methyl Abietate, Jojoba Oil, Lemongrass Essential Oil, Magnesium Sulfate, Olive Oil, Polyaminopropyl Biguanide, Polyglycerol-10 Laurate, Rosemary Essential Oil, Sorbitan Stearate, Sunflower Oil, Tocopherols (Vitamin E), Water.

Other Information: Contains no nano particles.

Protect this product from excessive heat and direct sun.

Maui Natural Organics

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MAUI NATURALS ALL NATURAL SUNSCREEN

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58918-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
POLYGLYCERYL-10 LAURATE (UNII: MPJ2Q8W18G)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
JOJOBA OIL (UNII: 724GKU717M)	

HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)
OLIVE OIL (UNII: 6UYK2W1W1E)
ROSEMARY OIL (UNII: 8LGU7VM393)
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)
HYDROGENATED METHYL ABIETATE (UNII: A23O709X8O)
WATER (UNII: 059QF0K00R)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
SUNFLOWER OIL (UNII: 3W1JG795YI)
TOCOPHEROL (UNII: R0ZB2556P8)
POLIHEXANIDE (UNII: 322U039GMF)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58918-002-02	90 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/10/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/10/2014	

Labeler - Hawaiian Classic Perfumes, Inc. (103409512)