

## **HAWAIIAN NATURAL ZINC SUNSCREEN SPF 50- zinc oxide lotion**

### **Kokua Sun Care**

*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.*

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### **Hawaiian Natural Zinc Sunscreen SPF 50**

Active Ingredient Purpose

Zinc Oxide 25% 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.

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs

Warnings:

- For external use only
- Do not use on broken skin
- When using this product keep out of eyes

Directions

- Apply generously 15 minutes before sun exposure
- Reapply:
  - After 80 minutes if 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 am-2pm.
  - Wear long-sleeve shirts, pants, hats, and sunglasses.
  - Children under 6 months: ask a doctor.

#### **Inactive Ingredients**

Water (Aqua), Aloe Barbadensis Leaf Juice, Caprylyl Caprylate/Caprinate, Macadamia Ternifolia Seed (Macadamia Nut) Oil, Aleurites Moluccana Seed (Kukui nut) oil, Polyglyceryl-2 Oleate, Polyhydroxystearic Acid, Glycerin, Cocos Nucifera (Coconut) Oil, Cetyl Dimethicone, Magnesium Sulfate, Hydrogenated Methyl Abietate, Galactoarabinan, Propanediol, Polyglyceryl-2 Stearate, KonaRed Hawaiian Coffee Fruit Extract, Morinda Citrifolia Fruit Juice (Noni), Arthrospira Platensis (Hawaiian Spirulina), Oryza Sativa (Rice) Bran Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Helianthus Annuus (Sunflower) Seed Extract, Caprylic/Capric Triglyceride, Prunus Armeniaca (Apricot) Fruit Extract, Musa Sapientum (Banana) Fruit Extract, Santalum Album (Sandalwood) Extract,

Butter Extract, Coffea Arabica (Coffee) Leaf/seed Extract, Pyrus Malus (Apple) Fruit Extract, Cocos Nucifera (Coconut) Fruit Extract, Helianthus Annuus (Sunflower) Seed Oil, Tocopherol, Plumeria Alba Flower Extract, Kaolin, Hydrogenated Vegetable Oil, 1,2-Hexanediol, Caprylhydroxamic Acid

Hawaiian Natural Zinc Sunscreen

Broad Spectrum SPF 50

Water Resistant 80 minutes

89 mL / 3 FL OZ

DA KINE SUNSCREEN • EASY TO APPLY • REEF SAFE • SUPPORTS LOCAL BUSINESS FERMETURE

Kōkua Sun Care™

presents



SPF 50

**HAWAIIAN NATURAL ZINC SUNSCREEN**  
BROAD SPECTRUM SPF 50  
WATER RESISTANT 80 MINUTES



featuring

**7 HAWAII GROWN ANTIOXIDANT INGREDIENTS**

KONARED® HAWAIIAN COFFEE FRUIT EXTRACT  
NONI ✻ SPIRULINA ✻ PLUMERIA ✻ HONEY  
MACADAMIA & KUKUI NUT OIL



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89 ML / 3 FL OZ

NO CHEMICAL SUNSCREENS • NO FRAGRANCE • NO PHTHALATES • NO PARABENS

**KOKUA SUN CARE™**  
HAWAIIAN SUPERFOOD FOR THE SKIN  
HIGH PERFORMANCE UVA + UVB PROTECTION

**Drug Facts**

Active Ingredient	Purpose
Zinc Oxide 25.0%	Sunscreen

**Uses**

- Helps prevent sunburn
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- When using this product keep out of eyes. Rinse with water to remove.
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**Other Information**

Protect this product from excessive heat and direct sun.

**WWW.KOKUASUNCARE.COM**

Manufactured for: Kōkua Sun Care LLC • Honolulu, HI

CIERRE | CLOSURE | FERMETURE

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**HAWAIIAN NATURAL ZINC SUNSCREEN SPF 50**

zinc oxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72096-101
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>KUKUI NUT OIL</b> (UNII: TP11QR7B8R)	
<b>PLUMERIA ALBA FLOWER</b> (UNII: LGC8P2PC4H)	
<b>CETYL DIMETHICONE 25</b> (UNII: U4AS1BW4ZB)	
<b>MAGNESIUM SULFATE ANHYDROUS</b> (UNII: ML30MJ2U7I)	
<b>ARABICA COFFEE BEAN</b> (UNII: 3SW678MX72)	
<b>COCONUT</b> (UNII: 3RT3536DHY)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>VANILLA</b> (UNII: Q74T35078H)	
<b>CAPRYLYL CAPRYLATE/CAPRATE</b> (UNII: 22MCG4RSMR)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>APRICOT</b> (UNII: 269CJD5GZ9)	
<b>MUSKMELON</b> (UNII: ZV095H5633)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>GALACTOARABINAN</b> (UNII: SL4SX1O487)	
<b>MACADAMIA OIL</b> (UNII: 515610SU8C)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>HYDROGENATED METHYL ABIETATE</b> (UNII: A23O709X8O)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>POLYGLYCERYL-2 STEARATE</b> (UNII: 253MC0P0YV)	
<b>COFFEA ARABICA FRUIT</b> (UNII: HOX6BEK27Q)	
<b>NONI FRUIT JUICE</b> (UNII: 6ULF85Z07J)	
<b>ARTHROSPIRA PLATENSIS</b> (UNII: 9L3TIH1UUE)	
<b>RICE BRAN</b> (UNII: R60QEP13IC)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>CRANBERRY</b> (UNII: 0MVO31Q3QS)	
<b>BANANA</b> (UNII: 4AJZ4765R9)	
<b>APPLE</b> (UNII: B423VGH5S9)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>SANDALWOOD</b> (UNII: 3641YW25N2)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72096-101-01	89 g in 1 BOX; Type 0: Not a Combination Product	02/10/2018	
2	NDC:72096-101-02	30 g in 1 BOX; Type 0: Not a Combination Product	06/12/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/10/2018	

**Labeler** - Kokua Sun Care (081062410)

## Establishment

Name	Address	ID/FEI	Business Operations
Vege Labs LLC.		117878620	manufacture(72096-101)

Revised: 6/2023

Kokua Sun Care