

## **E-KO SKIN CARE SPF 50- zinc oxide lotion**

### **E-Ko Beach Life Limited**

*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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### **e-ko SKIN CARE SPF 50**

#### ***Drug Facts***

#### ***Active Ingredients***

Non-Nano Zinc Oxide 25.0%

#### ***Purpose***

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 generously 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 the sun, especially from 10am - 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/Caprates, Macadamia Ternifolia Seed (Macadamia Nut) Oil, Aleurites Moluccana Seed (Kuki Nut) Oil, Polyglyceryl-2 Oleate, Polyhydroxystearic Acid, Glycerin, Cocos Nucifera (Coconut) Oil, Cetyl Dimethicone, Magnesium Sulfate, Hydrogenated Methyl Abietate, Galactarabinan, Propanediol, Polyglyceryl-2

Stearate, KonaRed® Hawaiian Coffee Fruit Extract, Morinda Citrifolia Honey (Noni honey), Organic 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, Vanilla Planifolia Fruit Extract, Cucumis Melo Cantalupensis (Cantaloupe) Fruit Extract, Vaccinium Macrocarpon (Cranberry) 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.

### ***Other Information***

Protect this product from excessive heat and direct sun.

**SAFE FOR MARINE LIFE. SAFE FOR YOUR FACE AND YOUR BODY. SAFE FOR REEFS**

**WATER RESISTANT**

**80 MIN SUNSCREEN**

**BROAD SPECTRUM SPF 50+**

NON- NANO ZINC OXIDE

SEVEN HAWAIIAN ANTIOXIDANT INGREDIENTS

OCTINOXATE AND OXYBENZONE FREE

**MANUFACTURED FOR**

**E-Ko Beach Life LLC**

**North Wales, PA**

VISIT [EKOBEACHLIFE.COM](http://EKOBEACHLIFE.COM)

**MADE IN THE U.S.A**

**USING FOREIGN & DOMESTIC MATERIALS**

POWERED BY **Kokua Sun Care®**

### **Packaging**



Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Non-Nano Zinc Oxide 25.0%	Sunscreen
<b>Uses</b>	
<ul style="list-style-type: none"> <li>Helps prevent sunburn</li> <li>If used as directed with other sun protection measures (see <b>Directions</b>), decreases the risk of skin cancer and early skin aging caused by the sun</li> </ul>	
<b>Warnings</b>	
<ul style="list-style-type: none"> <li><b>For external use only</b></li> <li>Do not use on damaged or broken skin</li> <li>When using this product keep out of eyes. Rinse with water to remove.</li> <li>Stop use and ask a doctor if rash occurs</li> <li><b>Keep out of reach of children.</b> If product is swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Apply generously 15 minutes before sun exposure</li> <li>Reapply: <ul style="list-style-type: none"> <li>After 80 minutes of swimming or sweating</li> <li>Immediately after towel drying</li> <li>At least every 2 hours</li> </ul> </li> <li><b>Sun Protection Measures:</b> 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: <ul style="list-style-type: none"> <li>Limit time in the sun, especially from 10am - 2pm</li> <li>Wear long-sleeve shirts, pants, hats, and sunglasses</li> </ul> </li> <li>Children under 6 months: ask a doctor</li> </ul>	
<b>Inactive Ingredients</b>	
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<b>Other Information</b>	
Protect this product from excessive heat and direct sun.	

MANUFACTURED FOR:  
E-Ko Beach Life LLC  
North Wales, PA  
VISIT [EKOBEACHLIFE.COM](http://EKOBEACHLIFE.COM)

MADE IN THE U.S.A  
USING FOREIGN &  
DOMESTIC MATERIALS



POWERED BY  
**Kokua Sun Care®**

3 FL OZ / 89 ML

## E-KO SKIN CARE SPF 50

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:736 18-00 1
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL CAPRYLATE/CAPRATE (UNII: 22MCG4RSMR)	
MACADAMIA OIL (UNII: 515610SU8C)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
POLYGLYCERYL-2 OLEATE (UNII: 5759J47SAM)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
HYDROGENATED METHYL ABIETATE (UNII: A23O709X8O)	
GALACTOARABINAN (UNII: SL4SX1O487)	
PROPANEDIOL (UNII: 5965N8W85T)	
POLYGLYCERYL-2 STEARATE (UNII: 253MC0P0YV)	
COFFEA ARABICA FRUIT (UNII: HOX6BEK27Q)	
NONI FRUIT JUICE (UNII: 6ULF85Z07J)	
ARTHROSPIRA PLATENSIS (UNII: 9L3TIH1UUE)	
RICE BRAN (UNII: R60QEP13IC)	
ROSEMARY (UNII: IJ67X351P9)	
SUNFLOWER SEED (UNII: R9N3379M4Z)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
APRICOT (UNII: 269CJD5GZ9)	
VANILLA BEAN (UNII: Q74T35078H)	
MUSKMELON (UNII: ZV095H5633)	
CRANBERRY (UNII: 0MVO31Q3QS)	
BANANA (UNII: 4AJZ4765R9)	
SANDALWOOD (UNII: 3641YW25N2)	
ARABICA COFFEE BEAN (UNII: 3SW678MX72)	
APPLE (UNII: B423VGH5S9)	
COCONUT (UNII: 3RT3536DHY)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PLUMERIA ALBA FLOWER (UNII: LGC8P2PC4H)	
KAOLIN (UNII: 24H4NWX5CO)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73618-001-01	89 mL in 1 TUBE; Type 0: Not a Combination Product	03/25/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/25/2020	

**Labeler** - E-Ko Beach Life Limited (117387123)

Revised: 2/2020

E-Ko Beach Life Limited