HAWAIIAN NATURAL ZINC SUNSCREEN BROAD SPECTRUM TINTED SPF 30zinc oxide cream 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.

Hawaiian Natural Zinc Sunscreen Broad Spectrum Tinted SPF 30

Active Ingredients

Non Nano Zinc Oxide 18%

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

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 damaged skin
- When using this product keep out of eyes. Rinse with water to remove

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

Water (Aqua), Aloe Barbadensis Leaf Juice, Coco-caprylate/Caprate, Glycerin, Macademia (Ternifolia) Seed Oil, Kukui Seed(Aleurites Moluccana) Oil, Polyglyceryl-2 Oleate, Polyhydroxystearic Acid, Hydrogenated Methyl Abietate, Magnesium Sulfate, Galactoarabinan, Diheptyl Succinate, Capryloyl Glycerin/Sebacic Acid Copolymer, Propanediol, Polyglyceryl-2 Stearate, Caprylic/Capric Triglyceride, Noni (Morinda Citrifola)

Fruit Extract, Spirulina (Arthrospira Platensis), Rosmarinus Officinalis (Rosemary) Leaf Extract, Helianthus Annuus (Sunflower) Seed Oil, Coffea Arabica (Coffee) Leaf/Seed Extract, Vanilla planifolia Fruit Extract, Prunus Armeniaca (Apricot) Fruit Extract, Cinnamomium Zeylanicum Bark Extract, Kaolin, Hydrogenated Vegetable Oil, Helianthus Annuus (Sunflower) Seed Oil, Plumeria Alba Flower Extract, Tetrasodium Glutamate Diacetate, Caprylhydroxamic Acid, Sodium Levulinate, Sodium Anisate, Iron oxides

Kokua Sun Care

Tinted SPF 30

Hawaiian Natural Zinc Sunscreen Broad Spectrum SPF 30

80 Minutes

Water Resistant

89 ML/ 3 FL OZ



KOKUA SUN CARE®

HAWAIIAN SUPERFOOD FOR THE SKIN
HIGH PERFORMANCE UVA + UVB PROTECTION

Drug Facts

Active Ingredients
Non Nano Zinc Oxide 18 %

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 af 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:
- •Children under 6 months: ask a doctor

Ingredients

Water (Aqua), Aloe Barbadensis Leaf Juice, Coco-Caprylate/Caprate, Glycerin, Macadamia (Ternifolia) Seed Oil*, Kukui Seed(Aleurites Moluccana) Oil*, Polyglyceryl-2 Oleate, Polyhydroxystearic Acid, Hydrogenated Methyl Abietate, Magnesium Sulfate, Galactoarabinan, Diheptyl Succinate, Capryloyl Glycerin/Sebacic Acid Copolymer, Propanediol, Polyglyceryl-2 Stearate, Caprylic/Capric Triglyceride, Noni (Morinda Citrifolia) Fruit Extract*, Spirulina (Arthrospira Platensis)*, Rosmarinus Officinalis (Rosemary) Leaf Extract, Heliantus Annuus (Sunflower) Seed Oil, Coffea Arabica (Coffee) Leaf/Seed Extract, Vanilla Planifolia Fruit Extract, Prunus Armeniaca (Apricot) Fruit Extract, Cinnamomum Zeylanicum Bark Extract, Prunus Armeniaca (Apricot) Fruit Extract, Cinnamomum Zeylanicum Bark Extract, Kaolin, Hydrogenated Vegetable Oil, Heliantus Annuus (Sunflower) Seed Oil, Plumeria Alba Flower Extract*, Tetrasodium Glutamate Diacetate, Caprylhydroxamic Acid, Sodium Levulinate, Sodium Anisate, Iron Oxides *HAWAII GROWN INGREDIENTS

Other Information

Protect this product from excessive heat and direct sun.

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HAWAIIAN NATURAL ZINC SUNSCREEN BROAD SPECTRUM TINTED SPF 30

zinc oxide cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:7209	-102
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Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	18 g in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PLUMERIA ALBA FLOWER (UNII: LGC8P2PC4H)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
MACADAMIA OIL (UNII: 515610SU8C)	
ARABICA COFFEE BEAN (UNII: 3SW678MX72)	
KAOLIN (UNII: 24H4NWX5CO)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-2 OLEATE (UNII: 5759J47SAM)	
GALACTOARABINAN (UNII: SL4SX1O487)	
DIHEPTYL SUCCINATE (UNII: 057N7SS26Y)	
PROPANEDIOL (UNII: 5965N8W85T)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
SODIUM LEVULINATE (UNII: VK44E1MQU8)	
SODIUM ANISATE (UNII: F9WFJ28MV9)	
VANILLA BEAN (UNII: Q74T35078H)	
APRICOT (UNII: 269CJD5GZ9)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
POLYGLYCERYL-2 STEARATE (UNII: 253MC0P0YV)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
HYDROGENATED METHYL ABIETATE (UNII: A230709X80)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
NONI FRUIT (UNII: 7829X3G2X5)	
ARTHROSPIRA PLATENSIS (UNII: 9L3TIH1UUE)	
ROSEMARY (UNII: IJ67X351P9)	
CINNAMON BARK OIL (UNII: XE54U569EC)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72096-102-	89 mL in 1 BOTTLE; Type 0: Not a Combination	04/19/2022	

1 01	Product	U4/ 10/ 2U 2 3		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph fina	M020	04/18/2023		

Labeler - Kokua Sun Care (081062410)

Revised: 4/2023 Kokua Sun Care