

EEZYSUN SPF 50- titanium dioxide, zinc oxide cream
BIO EARTH MANUFACTURING (PTY) LTD

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.

Purpose

Sunscreen

Uses

Helps prevent sunburn and protects against insects
If used as directed with other sun protection measures (**See Directions**) decreases the risk of skin cancer

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 doctor if** rash occurs
- **Keep out of reach of children**

Direction

- Apply liberally 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. Use a broad spectrum sun-screen with an SPF value of 50 or higher
- limit time in the sun, especially from 10 am - 2 pm
- wear long-sleeve shirts, pants, hats and sunglasses
- Children under 6 months of age: ask a doctor

Other information

store at or below 77° F . Do not use if seal is broken

Inactive ingredients

Aloe Barbadosis Leaf Oil, Aqua, Ascorbic Acid, Baryte,Cetearyl Alcohol, Cetearyl Glucoside, Citric Acid, Citronella,Citrullus Vulgaris (Kalahari Melon) Oil, Glycerine, Glyceryl Stearate, Glycine Soja (Soybean) Oil, Hydroxyethyl Cellulose,Lemongrass, Neem,

Polysorbate 20, Potassium Cetyl Phosphate, Potassium Sorbate, Retinol Palmitate, Ricinus Communis (Castor) Seed Oil (and) Hydrogenated Castor Oil (and) Copernicia Cerifera (Carnauba) Wax, Rosa Mosqueta (Rosehip) Fruit, Sodium Benzoate, Sodium Lactate, Sorbitan Oliviate, Tocopheryl Acetate, Vanilla Planifolia Fruit Oil

Active ingredients

Zinc Oxide 10%, Titanium Dioxide 8%

Product label

Drug Facts	
Active ingredients Zinc Oxide 10%, Titanium Dioxide 8%	Purpose Sunscreen
Uses <ul style="list-style-type: none"> helps prevent sunburn and protects against insects if used as directed with other sun protection measures (<i>see Directions</i>), decreases the risk of skin cancer 	
Warnings For external use only	
Do not use <ul style="list-style-type: none"> on damaged or broken skin 	
When using this product <ul style="list-style-type: none"> keep out of eyes rinse with water to remove 	
Stop use and ask doctor if <ul style="list-style-type: none"> rash occurs 	
Keep out of reach of children	
Directions <ul style="list-style-type: none"> Apply liberally 15 minutes before sun exposure. Reapply: <ul style="list-style-type: none"> after 80 minutes of swimming or sweating immediately after towel drying at least every 2 hours Sun protection measures. Use a broad spectrum sunscreen with an SPF value of 50 or higher <ul style="list-style-type: none"> limit time in the sun, especially from 10 am - 2 pm wear long-sleeve shirts, pants, hats and sunglasses Children under 6 months of age: ask a doctor 	
Other information <ul style="list-style-type: none"> store at or below 77 °F. Do not use if seal is broken 	
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Product of South Africa

DERMATOLOGICALLY APPROVED

NO ADDED PARABENS



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Manufacturer:
BioEarth Manufacturing (Pty) Ltd 639768436

Distributed by:
EezyBrands Corporation,
8 The Green, Suite #5350,
Dover, DE 19901, USA

EEZYSUN

Natural Protection. Scientifically Proven.

50

SPF

SUNSCREEN

BROAD SPECTRUM SPF 50

Insect Repellent | Water Resistant (80 minutes)

3.3 fl oz (100 ml)

WITH CITRONELLA

MARINE-FRIENDLY

EEZYSUN SPF 50

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70116-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	8 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CITRONELLA OIL (UNII: QYO8Q067D0)	
CITRUS X LIMON FLOWERING TOP OIL (UNII: 4C38SS0J60)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SOYBEAN OIL (UNII: 241ATL177A)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
CYMBOPOGON CITRATUS LEAF (UNII: 06JMS448M5)	
AZADIRACHTA INDICA SEED OIL (UNII: 4DKJ9B3K2T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
CASTOR OIL (UNII: D5340Y2I9G)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
ROSA MOSCHATA OIL (UNII: J99W255AWF)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VANILLA PLANIFOLIA OIL (UNII: 0A3F415158)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:70116-014-01	70 in 1 CARTON	06/30/2023	
1		100 mL in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part352		06/30/2023	

Labeler - BIO EARTH MANUFACTURING (PTY) LTD (639768436)

Establishment			
Name	Address	ID/FEI	Business Operations
BIO EARTH MANUFACTURING (PTY) LTD		639768436	manufacture(70116-014)

Revised: 6/2023

BIO EARTH MANUFACTURING (PTY) LTD