

**EEZYSUN SPF50 BABIES AND KIDS- titanium dioxide, zinc oxide cream  
BIO EARTH MANUFACTURING (PTY) LTD**

-----

***Active ingredients***

Titanium Dioxide 3.5%, Zinc Oxide 9.5%

***Purpose***

Topical SPF50 Sun Cream for the prevention of sun burn

***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 doctor if** rash occurs

**Keep out of reach of children**

***Direction***

Apply liberally 15 minutes before sun exposure

Reapply after 40 minutes if swimming or sweating

immediately after towel drying

at least every two hours

**Sun protection measures** use a broad-spectrum sunscreen with an SPF value of 50 or higher

limit time in the sun, especially from 10am - 2pm

wear long-sleeve shirts, pants, hats, 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

Protect the product in this container from excessive heat and direct sun

***Inactive ingredients***

Aloe Vera, Ascorbic Acid, Barium Sulphate, Bulbinella, Carnauba, Castor Seed Oil, Cetearyl Alcohol, Chamomile Oil, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Hydrogenated Castor Oil, Hydroxyethyl Cellulose, Phenoxyethanol, Rosehip, Soybean Oil, Tocopheryl Acetate, Water, Xanthan Gum

## Product label

<b>Drug Facts</b>	
<b>Active ingredients</b> Zinc Oxide 9.5 %, Titanium Dioxide 3.5 %	<b>Purpose</b> 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 <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun</li> </ul>	
<b>Warnings</b> For external use only <b>Do not use</b> on damaged or broken skin <b>When using this product</b> keep out of eyes rinse with water to remove <b>Stop use and ask doctor if</b> rash occurs Keep out of reach of children	
<b>Directions</b> <ul style="list-style-type: none"> <li>apply liberally 15 minutes before sun exposure</li> <li>Reapply             <ul style="list-style-type: none"> <li>after 40 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> use a broad spectrum sunscreen with an SPF value of 50 or higher             <ul style="list-style-type: none"> <li>limit time in the sun, especially from 10 am - 2 pm</li> <li>wear long-sleeve shirts, pants, hats and sunglasses</li> </ul> </li> <li>children under 6 months of age: ask a doctor</li> </ul>	
<b>Other information</b> <ul style="list-style-type: none"> <li>store at or below 77 °F. Do not use if seal is broken</li> <li>protect the product in this container from excessive heat and direct sun</li> </ul>	
<b>Inactive ingredients</b> Aloe Vera, Ascorbic Acid, Barium Sulphate, Bulbinella, Carnauba, Castor Seed Oil, Cetearyl Alcohol, Chamomile Oil, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Hydrogenated Castor Oil, Hydroxyethyl Cellulose, Phenoxyethanol, Rosehip, Soybean Oil, Tocopheryl Acetate, Water, Xanthan Gum	

Product of South Africa  
 Manufacturer: BioEarth Manufacturing (Pty) Ltd 639768436  
 Distributed by: EezyBrands Corporation, 8 The Green, Suite #5350, Dover, DE 19901, USA

7 54590 26038 1

Non-Oily | Water Resistant (40 minutes)

3.3 fl oz (100 ml)

WITH ALOE VERA

MARINE-FRIENDLY

## EEZYSUN SPF50 BABIES AND KIDS

titanium dioxide, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70116-013
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	3.5 g in 100 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	9.5 g in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ALOE VERA LEAF POLYSACCHARIDES (UNII: W21O437517)				
ASCORBIC ACID (UNII: PQ6CK8PD0R)				
BARIUM SULFATE (UNII: 25BB7EKE2E)				
BULBINE FRUTESCENS WHOLE (UNII: M2U1C7UW6Y)				
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
CASTOR OIL (UNII: D5340Y2I9G)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
GLYCERIN (UNII: PDC6A3C0OX)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)				
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
ROSA MOSCHATA OIL (UNII: J99W255AWF)				
SOYBEAN OIL (UNII: 241ATL177A)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
WATER (UNII: 059QF0KO0R)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70116-013-01	70 in 1 CARTON	08/31/2022	
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 Drug	M020	08/31/2022		

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

## Establishment

Name	Address	ID/FEI	Business Operations
BIO EARTH MANUFACTURING (PTY) LTD		639768436	manufacture(70116-013)

Revised: 10/2024

BIO EARTH MANUFACTURING (PTY) LTD