

**EEZY PRO SPF30- meradimate, octinoxate, octocrylene, 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.

Eezy Pro

Actives

Meradimate, Octinoxate, Octocrylene, Titanium Dioxide, Zinc Oxide

Purpose

Sunsreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures decreases the risk of skin cancer and early skin aging caused by sun(see Directions)

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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure

Reapply

- After 40 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 value of 15 or higher and other sun protection measures including:
 - Limited time in the sun, especially from 10 a.m - 2 p.m
 - Wear long-sleeved shirts, pants, hats and sunglasses
- Children under 6 months of age: ask a doctor

Inactive ingredients

Aloe barbadensis leaf juice, Cellulose gum, Cetearyl alcohol, Glycerin, Glycerol Stearate, Methylparaben, Phenoxyethanol, Propylparaben, Vitamin A & E, Water, White petrolatum, Xanthan gum

Other information

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

Product Label

Drug Facts	
Active Ingredients Meradimate 3 %, Octinoxate 7.5 %, Octocrylene 4 %, Titanium Dioxide 5 %, Zinc Oxide 9 %	Purpose } ... Sunscreen
Uses <ul style="list-style-type: none"> ■ Helps prevent sunburn ■ If used as directed with other sun protection measures decrease the risk of skin cancer and early skin aging caused by the sun (see Directions) 	
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. If swallowed, get medical help or contact a Poison Control Center right away	
Directions <ul style="list-style-type: none"> ■ Apply liberally 15 minutes before sun exposure Reapply <ul style="list-style-type: none"> ■ After 40 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 value of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> ■ Limited 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"> ■ Protect the product in this container from excessive heat and direct sun 	
Inactive Ingredients Aloe barbadensis leaf juice, cellulose gum, cetearyl alcohol, glycerin, glycerol stearate, hydrolysed soybean fibre, methylparaben, niacinamide, phenoxyethanol, propylparaben, vitamin A & E, water, white petrolatum, xanthan gum	

Product of South Africa

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EEZY PRO SPF30

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70 116-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MERADIMATE (UNII: J9QGD60OUZ) (MERADIMATE - UNII:J9QGD60OUZ)	MERADIMATE	3 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5 g in 100 mL
ZINC OXIDE (UNII: SO2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	9 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BULBINE FRUTESCENS WHOLE (UNII: M2U1C7UW6Y)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
VITAMIN A (UNII: 81G40H8B0T)	
WATER (UNII: 059QF0K00R)	
PETROLATUM (UNII: 4T6H12BN9U)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70116-006-01	100 mL in 1 POUCH; Type 0: Not a Combination Product	03/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/17/2020	

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

Name	Address	ID/FEI	Business Operations
BIO EARTH MANUFACTURING (PTY) LTD		639768436	manufacture(70116-006)