

**EEZY PRO SPF 30- 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.*

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**Eezy Pro**

**Actives**

Meradimate, Octinoxate, Octocrylene, Titanium Dioxide, Zinc Oxide

**Purpose**

Sunscreen

**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 SPF30**



**EEZY PRO SPF 30**

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**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70 116-004
<b>Route of Administration</b>	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: SOI2LOH54Z) (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: HIE492ZZ3T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
VITAMIN A (UNII: 81G40H8B0T)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
XANTHAN GUM (UNII: TTV12P4NEE)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70116-004-01	10 in 1 PACKET	03/17/2020	
1		8 mL in 1 POUCH; 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	03/17/2020	

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

Name	Address	ID/FEI	Business Operations
BIO EARTH MANUFACTURING (PTY) LTD		639768436	manufacture(70116-004)