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, espesially 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

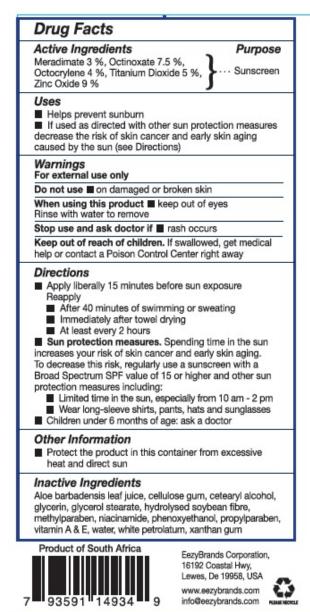
Aloe barbadensis leaf juice, Cellulose gum, Cetearyl alcohol, Glycerin, Glycerol Stearate, Methylparaben, Phenoxyethanol, Propylparaben,

Vitamin A & E, Water, White petrolatum, Xanthan gum

Other information

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

Product Label





EEZY PRO SPF30

meradimate, octinoxate, octocrylene, titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70116-006
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 DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	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: K679 OBS 311)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
GLYCERIN (UNII: PDC6A3C0OX)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PHENO XYETHANOL (UNII: HIE49 2ZZ3T)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
.ALPHATO COPHEROL (UNII: H4N855PNZ1)		
VITAMIN A (UNII: 81G40 H8 B0 T)		
WATER (UNII: 059QF0KO0R)		
PETROLATUM (UNII: 4T6H12BN9U)		
XANTHAN GUM (UNII: TTV12P4NEE)		

ı	Pac	kaging			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NI	DC: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)	