

**AUSTRALIAN GOLD BOTANICAL MINERAL SUNSCREEN BROAD SPECTRUM SPF 50-titanium dioxide, zinc oxide lotion**

**Prime Enterprises Inc.**

*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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**Australian Gold Botanical Mineral Sunscreen Broad Spectrum SPF 50**

***Active Ingredients***

Titanium Dioxide 4%

Zinc Oxide 4%

***Purpose***

Sunscreen

***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 a doctor** if rash occurs

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

- 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.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 a.m. – 2 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses
  - children under 6 months: Ask a doctor

Alumina, Butyrospermum Parkii (Shea) Butter, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclopentasiloxane, Dimethicone Crosspolymer, Disodium EDTA, Distearidimonium Hectorite, Eucalyptus Globulus Leaf Extract, Fragrance, Glycerin, Hexyl Laurate, Panthenol, PEG-10

Dimethicone, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Porphyra Umbilicalis Extract, Silica, Squalane, Stearic Acid, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Tocopheryl Acetate, Water

**Other Information**

- protect this product from excessive heat and direct sun

**Questions or Comments?**

Call toll free 1-855-LIV-GOLD (548-4653)

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**Drug Facts**

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\*Vitamin E

HYPO-ALLERGENIC, OXYBENZONE FREE, PARABEN FREE, PABA FREE, PHTHALATE FREE, DERMATOLOGIST TESTED, PEDIATRICIAN TESTED, REEF FRIENDLY, NO ANIMAL TESTING

Also Non-Nano, SLS (Sulfate) Free, Petrolatum Free, Alcohol Free, Dye Free, Oil Free & BPA Free

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**AUSTRALIAN GOLD BOTANICAL MINERAL SUNSCREEN BROAD SPECTRUM SPF 50**

titanium dioxide, zinc oxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0237
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	43.04 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	43.04 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
SQUALANE (UNII: GW89575KF9)	
ALUMINUM OXIDE (UNII: LM26O6933)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SHEA BUTTER (UNII: K49155WL9Y)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
CYCLOMETHICONE 5 (UNII: 0THI5PC10R)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
PANTHENOL (UNII: WV9CM0O67Z)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
WATER (UNII: 059QF0K00R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	

## Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0237-4	147 mL in 1 TUBE; Type 0: Not a Combination Product	07/15/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part352	07/15/2016	
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**Labeler** - Prime Enterprises Inc. (101946028)

**Registrant** - Prime Enterprises Inc. (101946028)

**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0237) , manufacture(58443-0237) , label(58443-0237) , analysis(58443-0237)

Revised: 1/2020

Prime Enterprises Inc.