

**BEYOU BROAD SPECTRUM SPF 40 SUNSCREEN- 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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**BeYou Dialy Moisturizer Mineral Sunscreen Broad Spectrum SPF 40**

***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**

**Do not use** on damaged or broken skin

**When using this product**

**When using this product** keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor**

**Stop use and ask a doctor** if rash occurs

**Keep out of reach of children.**

**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 a 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

## **INACTIVE INGREDIENTS**

Allantoin, Alumina, Butyrospermum Parkii (Shea) Butter, Camellia Oleifera (Green Tea) Leaf Extract, Caprylic/Capric Triglyceride, Cetyl PEG/PPG-10/1 Dimethicone, Cucumis Sativus (Cucumber) Fruit Extract, Cyclopentasiloxane, Dimethicone Crosspolymer, Distearidimonium Hectorite, Ethylhexylglycerin, Glycerin, Hexyl Laurate, Iron Oxides (CI 77491), Iron Oxides (CI 77492), Iron Oxides (CI 77499), Linum Usitatissimum (Linseed) Seed Oil, Niacinamide, Oenothera Biennis (Evening Primrose) Oil, PEG-10 Dimethicone, Phenoxyethanol, Physalis Angulata Extract, Plankton Extract, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Rosa Canina Fruit Oil, Silica, Sodium Hyaluronate, Stearic Acid, Tocopheryl Acetate, Triethoxycaprylylsilane, Water

### ***Other Information***

- Protect this product from excessive heat and direct sun
- May stain some fabrics or surfaces

### ***Questions or Comments?***

Call Toll free 1-87742396877

**Australian Gold Botanical Tinted Face Broad Spectrum SPF 50 (non-Kakadu)**

# beyou.

## NIACINAMIDE

DAILY MOISTURIZER  
MINERAL SUNSCREEN

hydrate + UVA/UVB Protection

BROAD-SPECTRUM  
**SPF40**

PROTECTOR SOLAR/SUNSCREEN  
MINERAL HIDRATANTE  
PROTECCIÓN UVA/UVB

CRÈME SOLAIRE/SUNSCREEN  
MINÉRALE HYDRATANTE  
PROTECTION UVA/UVB

1.69 fl oz. (50 ml)

FRAGRANCE FREE

CRUELTY-FREE

FREE OF: PARABENS,  
SULFATES, PHTHALATES,  
ALCOHOL

### Drug Facts

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## BEYOU BROAD SPECTRUM SPF 40 SUNSCREEN

titanium dioxide, zinc oxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0627
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	42 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	42 mg in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>PHYSALIS ANGULATA</b> (UNII: W4TKW9D5GG)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>CAMELLIA OLEIFERA LEAF</b> (UNII: 5077EL0C60)	
<b>EVENING PRIMROSE OIL</b> (UNII: 3Q9L08K71N)	
<b>POLYMETHYLSILSESQUIOXANE (11 MICRONS)</b> (UNII: Z570VEV8XK)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2)</b> (UNII: V2W71V8T0X)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>CUCUMBER</b> (UNII: YY7C30VXJT)	
<b>LINSEED OIL</b> (UNII: 84XB4DV00W)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>ROSA CANINA FRUIT OIL</b> (UNII: CR7307M3QZ)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	

## Product Characteristics

<b>Color</b>	brown (Light Tan)	<b>Score</b>	
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<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0627-3	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	05/19/2023	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	manufacture(58443-0627) , label(58443-0627) , pack(58443-0627) , analysis(58443-0627)

Revised: 7/2023

Prime Enterprises Inc.