

**ETERNAL SPIRIT BEAUTY BROAD SPECTRUM SPF 30- 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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**Eternal Spirit Beauty Sunscreen Lotion Broad Spectrum SPF 30**

**Active ingredients**

Titanium Dioxide 3%

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 a broad spectrum SPF of 15 or higher and other sun protection measures including:
  - limit time in 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**

Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aluminum Hydroxide, Argania spinosa (Argan) Kernel Oil, C12-15 Alkyl Benzoate, Cetareth-20, Cetyl Alcohol, Dibutyl Adipate, Dimethicone, Glycerin, Hexyl Laurate, Iron Oxides, Lecithin, Magnesium Aluminum Silicate, Malus Domestica Fruit Cell Culture Extract, Methylisothiazolinone, PEG-12 Dimethicone, Phenoxyethanol, Polyglyceryl-3 Distearate, Stearic Acid, Stearyl Alcohol, Triethoxycaprylylsilane, Water (Aqua), Xanthan Gum

### **Other information**

- protect this product from excessive heat and direct sun.

### **Eternal Spirit Beauty Sunscreen Lotion Broad Spectrum SPF 30 Mineral Sunscreen**

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Titanium Dioxide 3% Zinc Oxide 4%	Sunscreen
<b>Uses</b>	
<ul style="list-style-type: none"> <li>Helps prevent sunburn</li> <li>If used as directed with other sun protection measures (<b>Directions</b>), decreases the risk of skin cancer and early skin aging caused by the sun.</li> </ul>	
<b>Warnings</b>	
<b>For external use only</b>	
<b>Do not use</b> on damaged or broken skin	
<b>When using this product</b> keep out of eyes. Rinse with water to remove	
<b>Stop use and ask a doctor</b> if rash occurs	
<b>Keep out of reach of children.</b> If product is swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>apply liberally 15 minutes before sun exposure</li> <li>reapply: <ul style="list-style-type: none"> <li>after 80 minutes of swimming or sweating</li> <li>immediately after towel drying</li> <li>at least every 2 hours</li> </ul> </li> <li><b>Sun Protection Measures.</b> 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: <ul style="list-style-type: none"> <li>limit time in the sun, especially from 10 a.m. - 2 p.m.</li> <li>wear long-sleeve shirts, pants, hats, and sunglasses.</li> <li>children under 6 months: Ask a doctor.</li> </ul> </li> </ul>	
<b>Inactive Ingredients</b>	
Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aluminum Hydroxide, Argania spinosa (Argan) Kernel Oil, C12-15 alkyl Benzoate, Ceteareth-20, Cetyl Alcohol, Dibutyl Adipate, Dimethicone, Glycerin, Hexyl Laurate, Iron Oxides, Magnesium Aluminum Silicate, Methylidithiazolinone, PEG-12 Dimethicone, Phenoxyethanol, Polyglyceryl-3 Distearate, Stearic Acid, Stearyl Alcohol, Triethoxycaprylsilane, Water (Aqua), Xanthan Gum, Malus Domestica Fruit Cell Culture Extract, Lecithin.	
<b>Other Information</b>	
<ul style="list-style-type: none"> <li>protect this product from excessive heat and direct sun.</li> </ul>	

Distributed by: Worldwide Cosmetics Inc.  
2019 NW 84th Ave Doral, FL 33122



ESB63-1



# SUNSCREEN LOTION



**Broad Spectrum SPF 30  
Mineral Sunscreen  
Water Resistant (80 Minutes)**

2 Fl oz / 59 mL

## ETERNAL SPIRIT BEAUTY BROAD SPECTRUM SPF 30

titanium dioxide, zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0413
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	31.2 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	41.6 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ARGAN OIL (UNII: 4V59G5UW9X)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
APPLE (UNII: B423VGH5S9)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

### Product Characteristics

Color	brown (Tan)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0413-3	59 mL in 1 TUBE; Type 0: Not a Combination Product	02/01/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/01/2016	

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

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

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Prime Enterprises, Inc.		101946028	label(58443-0413) , pack(58443-0413) , manufacture(58443-0413) , analysis(58443-0413)

Revised: 8/2021

Prime Enterprises, Inc.