

# **SUN BAD BROAD SPECTRUM SPF 50 MINERAL- 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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## **Sun Bad Sunscreen Lotion Broad Spectrum 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

***Inactive ingredients:***

Alumina, Butyrospermum Parkii (Shea) Butter, C13-15 Alkane, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Allantoin, Alumina, Butyrospermum Parkii (Shea) Butter, Camellia Oleifera (Green Tea) Leaf Extract, Cetyl PEG/PPG-10/1 Dimethicone, Cucumis Sativus (Cucumber) Extract, Cyclopentasiloxane, Dimethicone Crosspolymer, Disodium EDTA, Disteardimonium Hectorite, Ethylhexylglycerin, Fragrance, Glycerin, Hexyl Laurate, Linum Usitatissimum (Linseed) Seed Oil, Oenothera Biennis (Evening Primrose) Oil, PEG-10 Dimethicone, Phenoxyethanol, Plankton Extract, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Rosa Canina Seed Oil, Silica, Stearic Acid, Tocopheryl Acetate, Water

***Other information***

- protect this product from excessive heat and direct sun
- may stain or damage some fabrics or surfaces

***Questions or comments?***

Call toll free 1-423-267-3351

**Sun Bad Marshmallow Sunscreen Lotion Broad Spectrum SPF 50**



# SUN BAD SUNSCREEN PROTECTION FROM THE MEAN OLD SUN BROAD SPECTRUM SPF 50 MARSH MALLOW SCENTED LOTION WATER RESISTANT (80 MINUTES)



We made MoonPie Sun Bad Sunscreen because we're tired of the sun getting credit that our beautiful moon deserves. You think the moon would ever burn your skin or melt your chocolatey snacks? No way, pal. So, give a big ol' SPFU to that celestially-inferior ball of fire with this lovely marshmallow-scented lotion.



**THIS PRODUCT SMELLS LIKE MARSHMALLOW**  
Kinda... But no actual marshmallows were harmed in its making. Though we did think about it!

## Drug Facts

### 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 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, Cetyl PEG/PPG-10/1 Dimethicone, Cucumis Sativus (Cucumber) Fruit Extract, Cyclopentasiloxane, Dimethicone Crosspolymer, Disodium EDTA, Distearidimonium Hectorite, Ethylhexylglycerin, Fragrance, Glycerin, Hexyl Laurate, Linum Usitatissimum (Linseed) Seed Oil, Oenothera Biennis (Evening Primrose) Oil, PEG-10 Dimethicone, Phenoxyethanol, Plankton Extract, Polyglyceryl-4 Isostearate, Polymethylsilsequioxane, Rosa Canina Fruit Oil, Silica, Stearic Acid, Tocopheryl Acetate, Water

### Other information

- protect this product from excessive heat and direct sun
- may stain or damage some fabrics or surfaces

### Questions or comments?

Call toll free 1-423-267-3351

Distributed by  
MoonPie, 900 Manufacturers Rd, Chattanooga, TN 37405

3 FL. OZ.  
(88 ML)

## SUN BAD BROAD SPECTRUM SPF 50 MINERAL

titanium dioxide, zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0571
<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	42.4 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	42.4 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>LINSEED OIL</b> (UNII: 84XB4DV00W)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>CAMELLIA OLEIFERA LEAF</b> (UNII: 5077ELOC60)	
<b>CUCUMBER</b> (UNII: YY7C30VXJT)	
<b>EVENING PRIMROSE OIL</b> (UNII: 3Q9L08K71N)	
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	
<b>ROSA CANINA SEED</b> (UNII: 4503R1M9UT)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2)</b> (UNII: V2W71V8T0X)	
<b>DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

## Product Characteristics

<b>Color</b>	white (White to Off-White)	<b>Score</b>	
<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:58443-0571-3	88 mL in 1 TUBE; Type 0: Not a Combination Product	07/13/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	07/13/2022	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0571) , manufacture(58443-0571) , label(58443-0571) , analysis(58443-0571)

Revised: 9/2022

Prime Enterprises Inc.