

**ULTA BEAUTY 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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**ULTA Beauty 50 Sun Protection Broad Spectrum SPF 50 Sunscreen Mineral Lotion**

***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
- avoid contact with fabrics - could cause discoloration

***Questions or comments?***

Call 1-866-983-8582

**ULTA beauty Mineral Sunscreen Body Lotion Broad Spectrum SPF 50**

## 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

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### Directions

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• 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) 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  
• avoid contact with fabrics - could cause discoloration

### Questions?

1-866-983-8582

MADE WITHOUT PARABENS, PHTHALATES OR OXYBENZONE WHICH HAS BEEN SHOWN TO HARM CORAL REEFS • SANS PARABÈNE, PHTHALATE ET OXYBENZONE, UN COMPOSÉ CHIMIQUE NÉFASTE POUR LES RÉCIFS DE CORAIL

MADE IN USA FROM US & IMPORTED INGREDIENTS • FABRIQUÉ AUX ÉTATS-UNIS À PARTIR D'INGRÉDIENTS IMPORTÉS ET PROVENANT DES ÉTATS-UNIS  
DISTR. BY/PAR ULTA INC., BOLINGBROOK, IL 60440  
ULTA.COM



# ULTAbeauty®

## MINERAL SUNSCREEN BODY LOTION LOTION MINÉRALE POUR LE CORPS AVEC ÉCRAN SOLAIRE

BROAD SPECTRUM SPF 50  
FPS 50 À LARGE SPECTRE

# 50

WATER RESISTANT UP TO 80 MINS  
HYDROFUGE JUSQU'À 80 MINUTES

147 mL / 5 fl. oz.

## ULTA BEAUTY BROAD SPECTRUM SPF 50 MINERAL

titanium dioxide, zinc oxide lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0569
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	42.36 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	42.36 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: 5077EL0C60)	
<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:58443-0569-4	147 mL in 1 TUBE; Type 0: Not a Combination Product	04/29/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	04/29/2021	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0569) , manufacture(58443-0569) , label(58443-0569) , analysis(58443-0569)

