# UNSUN BROAD SPECTRUM SPF 15 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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## **Unsun Body Lotion Sunscreen Broad Spectrum SPF 15**

### **Active Ingredients**

Titanium Dioxide 1.75%, Zinc Oxide 3%

### 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 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 value of 15 or higher and other sun protection measures including:

Limit time in the sun, especially from 10 a.m. to 2 p.m. Wear long-sleeved shirts, pants, hats, and sunglasses Children under 6 months of age: Ask a doctor.

## **Inactive Ingredients**

Allantoin, Alumina, Butyrospermum Parkii (Shea) Butter, Camellia Oleifera (Green Tea) Leaf Extract, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cucumis Sativus (Cucumber) Extract, Cyclopentasiloxane, Dimethicone Crosspolymer, Disodium EDTA, Disteardimonium Hectorite, Glycerin, Hexyl Laurate, Lavandula Angustifolia (Lavender) Oil, 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

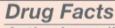
#### Other Information

protect this product from excessive heat and direct sun.

#### Questions or comments?

info@unsuncosmetics.com

**Unsun SPF 15 Mineral Body Lotion** 



## Active Ingredients Purpose

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 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 value of 15 or higher and other sun protection measures including: • Limit time in the sun, especially from 10 a.m. to 2 p.m. • Wear long-sleeved shirts, pants, hats, sunglasses • Children under 6 months of age: Ask a doctor.

Inactive Ingredients Alantoin, Alumina, Butyrospermum Parkii (Shea) Butter, Camellia Oleifera (Green Tea) Leaf Extract, Caprylyf Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cucumis Sativus (Cucumber) Extract, Cyclopentasiloxane, Dimethicone Crosspolymer, Disodium EDTA, Disteardimonium Hectorite, Glycerin, Hexyl Laurate, Lavandula Angustifolia (Lavender) Oil, 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.

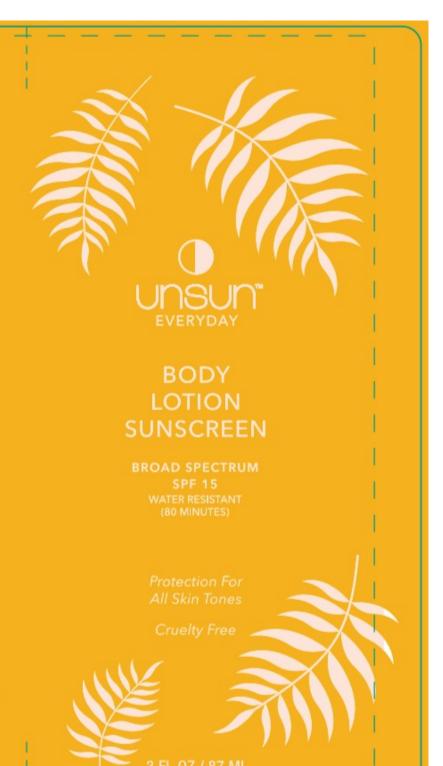
## Questions or comments?

info@unsuncosmetics.com

Made in the USA of foreign & domestic components
Dist by: UNSUN Cosmetics, Inc.
Woodland Hills, CA 91364







#### UNSUN BROAD SPECTRUM SPF 15 SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:58443-0305

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	18.375 mg in 1 mL		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	31.5 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	
CUCUMBER SEED (UNII: BT3S9L53JK)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
ROSA CANINA SEED (UNII: 4503R1M9UT)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DISTEARDIMO NIUM HECTO RITE (UNII: X687XDK09L)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
LINSEED OIL (UNII: 84XB4DV00W)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8 X80 D2L0)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAVENDER O IL (UNII: ZBP1YXW0 H8)	
ALLANTO IN (UNII: 344S277G0Z)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8 PR7V1SVM0)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
WATER (UNII: 059QF0KO0R)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820 DPX33S7)	
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SHEA BUTTER (UNII: K49 155WL9 Y)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

# Item Code Package Description Marketing Start Date Marketing End Date    1 NDC-50443-0205-2-07 white 1 THEF. Two 0. Nata Combination Products   02/20/2010	Packaging			
1 NDC-50.442 0.205 2 0.7 mJ in 1 TUDE: Town 0. Nat a Combination Product 0.2/20/20.40	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:58443-0305-3 87 mL in 110BE; Type 0: Not a Combination Product 03/28/2019	1 NDC:58443-0305-3	87 mL in 1 TUBE; Type 0: Not a Combination Product	03/28/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	03/28/2019		

## Labeler - Prime Enterprises Inc. (101946028)

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

Establishmen	t		
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		10 19 46 0 28	manufacture(58443-0305), label(58443-0305), analysis(58443-0305), pack(58443-0305)

Revised: 10/2020 Prime Enterprises Inc.