UNSUN BROAD SPECTRUM SPF 30 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.

Everyday by Unsun Light Medium Mineral Tinted Face Sunscreen Lotion SPF 30

Active ingredients

Titanium dioxide 3 %

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

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging **For external use only.**

Do not useon damaged or broken skin.

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If swallowed, call a poison control center or get medical help right away.

Directions

Apply liberally 15 minutes before sun exposure. Reapply after 80 minutes of swimming or sweating, at least every 2 hours. Children under 6 months of age: Ask a doctor. **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 value 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-sleeved shirts, pants, hats, and sunglasses.

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, Disteardimonium Hectorite, Ethylhexylglycerin, Glycerin, Hexyl Laurate, Iron Oxides, 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, Triethoxycaprylylsilane, Water

Other information

• protect this product from excessive heat and direct sun.

Questions or comments?

info@unsuncosmetics.com

Everyday by Unsun Light Medium Mineral Tinted Face Sunscreen Lotion SPF 30



MINERAL TINTED **FACE** SUNSCREEN LOTION

BROAD SPECTRUM **SPF 30**

WATER RESISTANT (80 MINUTES)

LIGHT - MEDIUM

Protection For All Skin Tones



1,7 FL 02 / 50 ML

Drug Facts

Active ingredients

Purpose Titanium dioxide 3%..... Zinc oxide 3%.....Sunscreen

Uses • helps prevent supburn • 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

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging For external use only.

Do not use on damaged or broken skin. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop use and ask a doctor if rash occurs, Keep out of reach of children, If swallowed, call a poison control center or get medical help right away.

Directions

Apply liberally and evenly before sun exposure. Reapply after 80 minutes of swimming or sweating, at least every 2 hours, Children under 6 months of age: Ask a doctor, 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.-2 p.m. Wear long-sleeved shirts, pants, hats, and sunglasses.

Inactive ingredients Alantoin, Alumina, Butyrospermum Parkii (Shea) Butter, Camella Oleifera (Green Tea) Leaf Extract, Cetyl PEG/PPG-10/1 Dimethicone, Cucumis Sativus (Cucumber) Extract, Cyclopentasiloxane, Dimethicone Crosspolymer, Disteardimonium Hectorite, Ethylhexyl-glycerin, Glycerin, Hexyl Laurate, Iron Oxides, 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, Triethoxycapry/silane, Water,

Other information • protect this product from excessive heat and direct sun,

Questions or comments?

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





UNSUN BROAD SPECTRUM SPF 30 MINERAL

titanium dioxide, zinc oxide lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:58443-0425

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	30.51 mg in 1 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	30.51 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
LAVENDER OIL (UNII: ZBP1YXW0H8)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)				
LINSEED OIL (UNII: 84XB4DV00W)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)				
CUCUMBER (UNII: YY7C30VXJT)				
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)				
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)				
ROSA CANINA SEED (UNII: 4503R1M9UT)				
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
ALUMINUM OXIDE (UNII: LMI26O6933)				
ALLANTOIN (UNII: 344S277G0Z)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
SHEA BUTTER (UNII: K49155WL9Y)				
WATER (UNII: 059QF0KO0R)				
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)				
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)				
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)				
GLYCERIN (UNII: PDC6A3C0OX)				
CYCLOMETHICONE 5 (UNII: 0THT5PCIOR)				
HEXYL LAURATE (UNII: 4CG9F9W01Q)				
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
FERRIC OXIDE YELLOW (UNII: EX43802MRT)				
D&C BLACK NO. 2 (UNII: 4XYU5U00C4)				

Product Characteristics			
Color	brown (Beige/Gray)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

1		50 mL in 1 TUBE; Type 0: Not a Combination Product	10/05/2021	
M	Marketing Information			
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ТО	C monograph fina	part352	10/05/2021	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0425), manufacture(58443-0425), label(58443-0425), analysis (58443-0425)

Revised: 10/2021 Prime Enterprises Inc.