

**UNSun 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.

Unsun Mineral Tinted Face Sunscreen Lotion Broad Spectrum 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

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, Cetyl PEG/PPG-10/1 Dimethicone, Cucumis Sativus (Cucumber) Extract, Cyclopentasiloxane, Dimethicone Crosspolymer, Distearidimonium 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

Unsun Mineral Tinted Face Sunscreen Lotion Broad Spectrum SPF 30

Drug Facts

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Titanium dioxide 3%	Sunscreen
Zinc oxide 3%	Sunscreen

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Woodland Hills, CA 91364 | unsuncosmetics.com



EVERYDAY
BY UNSUN™

MINERAL TINTED
FACE
SUNSCREEN
LOTION

BROAD SPECTRUM
SPF 30

WATER RESISTANT
(80 MINUTES)

Lightweight,
Matte Protection

Cruelty Free



1.7 FL OZ / 50 ML

UNSUN BROAD SPECTRUM SPF 30

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0389
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	31.5 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
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LINSEED OIL (UNII: 84XB4DV00W)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
SHEA BUTTER (UNII: K49155WL9Y)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ROSA CANINA SEED (UNII: 4503R1M9UT)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
ALLANTOIN (UNII: 344S277G0Z)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
CUCUMBER SEED (UNII: BT3S9L53JK)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0389-3	50 mL in 1 TUBE; Type 0: Not a Combination Product	02/16/2021	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	part352	02/16/2021	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(58443-0389) , label(58443-0389) , analysis(58443-0389) , pack(58443-0389)

Revised: 1/2021

Prime Enterprises, Inc.