

INFINITEK 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.

IINFINITEK PARIS Broad Spectrum SPF 50 Mineral Face 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:

Allantoin, Aloe Barbadensis Leaf Extract, Alumina, Bisabolol, Butyrospermum Parkii (Shea) Butter, Camellia Oleifera (Green Tea) Leaf Extract, Cetyl PEG/PPG-10/1 Dimethicone, Cyclopentasiloxane,

Dimethicone Crosspolymer, Disodium EDTA, Disteardimonium Hectorite, Ethylhexylglycerin, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hexyl Laurate, Panthenol, PEG-10 Dimethicone, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Silica, Stearic Acid, Tocopheryl Acetate, Water

Other information

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

Questions or comments?

dermaswiss@dermaswiss.com

Derma Swiss Broad Spectrum SPF 50 SUNSCREEN Mineral Lotion

Lightweight non-comedogenic emulsion, which filters and absorbs UVA and UVB sun rays.

Drug Facts

Active Ingredients:	Purpose
Titanium Dioxide 4% Zinc Oxide 4%	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, Aloe Barbadensis Leaf Extract, Alumina, Bisabolol, Butyrospermum Parkii (Shea) Butter, Camellia Oleifera (Green Tea) Leaf Extract, Cetyl PEG/PPG-10/1 Dimethicone, Cyclopentasiloxane, Dimethicone Crosspolymer, Disodium EDTA, Disteardimonium Hectorite, Ethylhexylglycerin, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hexyl Laurate, Panthenol, PEG-10 Dimethicone, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Silica, Stearic Acid, Tocopheryl Acetate, Water.

Other Information:

• protect this product from excessive heat and direct sun. • may stain some fabrics or surfaces

Questions or Comments:

dermaswiss@dermaswiss.com

DermaSwiss SWISS FORMULATIONS

Manufactured for:
Derma Swiss 3000 Mfg, Inc. Miami, FL 33122
www.dermaswiss.com

CONTAINS NO PARABENS, NO SULFATES, *NO OXYBENZONE WHICH HAS BEEN SHOWN TO HARM CORAL REEFS.



DermaSwiss®



DERMASUN

Sun Protector / Sunscreen

BROAD SPECTRUM SPF50

50

Water-Resistant
(80 minutes)

UVA/UVB Protection

Dermatologist Tested

Non-nano

Reef-Friendly*

MINERAL EMULSION

3 FL OZ / 89mL e

INFINITEK SPF 50 MINERAL

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0363
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	42.4 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	42.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	
ROSA CANINA SEED (UNII: 4503R1M9UT)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
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 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
ALUMINUM OXIDE (UNII: LM26O6933)	
ANACYSTIS NIDULANS EXTRACT (UNII: UV4FTL6UAW)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LINSEED OIL (UNII: 84XB4DV00W)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CUCUMBER (UNII: YY7C30VXJT)	

Product Characteristics

Color	brown (light tan)	Score	
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Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0363-3	50 mL in 1 TUBE; Type 0: Not a Combination Product	05/30/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/30/2019	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0363) , manufacture(58443-0363) , label(58443-0363) , analysis(58443-0363)

Revised: 10/2020

Prime Enterprises Inc.