

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.

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

Drug Facts

Active Ingredients Purpose

Titanium Dioxide 1.75%.....Sunscreen
Zinc Oxide 3%.....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, sunglasses • Children under 6 months of age: Ask a doctor.

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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.

Dist by: UNSUN Cosmetics, Inc.

Woodland Hills, CA 91364




unsun™
EVERYDAY

BODY
LOTION
SUNSCREEN

BROAD SPECTRUM
SPF 15
WATER RESISTANT
(80 MINUTES)

Protection For
All Skin Tones

Cruelty Free



3 FL OZ / 87 ML

UNSUN BROAD SPECTRUM SPF 15 SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0305
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	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)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
ROSA CANINA SEED (UNII: 4503R1M9UT)	
DIMETHICONE CROSSPOLYMER (45000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
LINSEED OIL (UNII: 84XB4DV00W)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
CYCLOMETHICONE 5 (UNII: 0TH5PCI0R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ALLANTOIN (UNII: 344S277G0Z)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM OXIDE (UNII: LM26O6933)	
WATER (UNII: 059QF0KO0R)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SHEA BUTTER (UNII: K49155WL9Y)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

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

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	manufacture(58443-0305) , label(58443-0305) , analysis(58443-0305) , pack(58443-0305)

Revised: 10/2020

Prime Enterprises Inc.