

DERMA E SUN DEFENSE SPF 30- zinc oxide and titanium dioxide lotion

derma e

DERMA E SUN DEFENSE SPF 30

Drug Facts

Active Ingredient	Purpose
Zinc Oxide 19.5% }	Sunscreen
Titanium Dioxide 2.64% }	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
- 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 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
 - reapply at least every 2 hours
 - use a water resistant sunscreen if swimming or sweating

Other information

- protect this product from excessive heat and direct sun

Inactive Ingredients

Aluminum Oxide, Ascorbic Acid, Camellia Sinensis Leaf Extract, Caprylic/Capric Triglyceride, Caprylyl Caprylate/Caprate, Cellulose Gum, Cetearyl Alcohol, Cetearyl Glucoside, Cetearyl Oliviate, Coco-Caprylate, Coco-Glucoside, Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate, Ethylhexylglycerin, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Isostearic Acid, Lecithin, Microcrystalline Cellulose, Panthenol, Phenoxyethanol, Phytic Acid, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, Purified Water, Sclerotium Gum, Butyrospermum Parkii (Shea) Butter, Sodium Phytate, Sorbitan Oliviate, Stearic Acid, Stearyl/Octyldodecyl Citrate Crosspolymer, Tocopheryl Acetate, Xanthan Gum.

***Certified Organic Ingredients**

Questions or comments?

Call toll free 1-800-933-9344 or visit dermae.com

Distributed by DERMA E®
Simi Valley, CA 93065, USA

PRINCIPAL DISPLAY PANEL - 113 g Tube Box

SUN CARE

New

&

Improved

FORMULA

DERMA • E

Sun Defense

Clear Zinc

Sunscreen

BROAD SPECTRUM

SPF 30

Mineral Clear Zinc Oxide

Vitamin E & Shea Butter

100% Unscented

spf

30

BODY

DERMATOLOGIST

RECOMMENDED

reef

safe

4 OZ / 113 g



Sun Defense
Clear Zinc
Sunscreen
SPF 30 Body



DERMA·E

Sun Defense
Clear Zinc
Sunscreen

BROAD SPECTRUM
SPF 30

Mineral Clear Zinc Oxide
Vitamin E & Shea Butter
100% Unscented



4 OZ / 113 g

Drug Facts

Active Ingredient	Purpose
Zinc Oxide (19.5%)	Sunscreen
Titanium Dioxide (2.64%)	Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see **Directions**),

decrease 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
- 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 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
 - reapply at least every 2 hours
 - use a water resistant sunscreen if swimming or sweating

Other information

- protect this product from excessive heat and direct sun

Inactive Ingredients Aluminum Oxide, Ascorbic Acid, Camellia Sinensis Leaf Extract, Caprylio/Caprio Triglyceride, Caprylyl Caprylate/Caprate, Cellulose Gum, Cetearyl Alcohol, Cetearyl Glucoside, Cetearyl Oliviate, Coco-Caprylate, Coco-Glucoside, Disostearyl Polyglyceryl-3 Dimer Diisoleate, Ethylhexylglycerin, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Isostearyl Acid, Lecithin, Microcrystalline Cellulose, Panthenol, Phenoxylethanol, Phytic Acid, Polyglyceryl-3 Polyminoleate, Polyhydroxystearic Acid, Purified Water, Sclerotium Gum, Butyrospermum Parkii (Shea) Butter, Sodium Phytate, Sorbitan Oliviate, Stearic Acid, Stearyl/Octyldodecyl Citrate Crosspolymer, Tocopheryl Acetate, Xanthan Gum.

*Certified Organic Ingredients

Questions or comments?

Call toll free 1-800-933-9344 or visit dermae.com

Best protection under the sun.

This lightweight, SPF 30 sunscreen offers broad spectrum protection in a formula that helps to reduce signs of aging and help protect skin from free radicals.

Eco-friendly, non-nano mineral clear Zinc Oxide* rubs in with no whitening and helps to shield your body from harmful UVA/UVB rays. Reef safe, hypoallergenic and fragrance-free, this antioxidant-rich formula with Vitamin E and Shea Butter leaves your skin feeling soft and fortified.

**We use only Non-Nano Mineral Zinc Oxide to keep our bodies and ecosystems healthy. Learn more at dermae.com*

Due to the use of some natural ingredients, the color of this product may slightly alter over time.

DERMA E offsets 100% of conventional electricity use with wind certificates.

Ethical Beauty

Clean, effective and dermatologist recommended, we are committed to your skin health, well-being and the natural environment. That's the DERMA E difference.



Since 1984, we are committed to skin health and safety:

- No Parabens
- No Phthalates
- No Formaldehyde
- No Petrolatum
- No Sulfates
- No Mineral Oils
- No Artificial Colors
- No Artificial Fragrances

We are committed to removing all non-recyclables and reducing plastic.



Distributed by DERMA E
50985-00476
800 933 9344 • dermae.com
Made in the USA or foreign
and domestic components

2103

DERMA E SUN DEFENSE SPF 30

zinc oxide and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54108-0418
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	195 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	26.4 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL CAPRYLATE/CAPRATE (UNII: 22MCG4RSMR)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
COCO-GLUCOSIDE (UNII: ICS790225B)	
DIISOSTEAROYL POLYGLYCERYL-3 DIMER DILINOLEATE (UNII: G3232Z5S2O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PANTHENOL (UNII: WW9CM0067Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FYTIC ACID (UNII: 7IGF0S7R8I)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
WATER (UNII: 059QF0KO0R)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	

SHEA BUTTER (UNII: K49155WL9Y)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL/OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: PN88NW0KPK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54108-0418-1	1 in 1 BOX	12/30/2022	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M020	12/30/2022	

Labeler - derma e (148940450)

Registrant - Topiderm, Inc. (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(54108-0418)

Revised: 7/2024

derma e