

## **DERMA E MINERAL SUNSCREEN MINERAL- zinc oxide powder derma e**

*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.*

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### **Derma E Mineral Sunscreen Mineral**

#### ***Drug Facts***

#### **Active Ingredients**

Titanium Dioxide 17.29%  
Zinc Oxide 20%

#### **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
- 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**

Camellia Sinensis Leaf Extract, Caprylic/Capric Triglyceride, Capryloyl Glycine, Chamomilla Recutita (Matricaria) Flower Extract, Mica, Potassium Sorbate, Silica, Sodium Benzoate, Tocopherol, Undecylenoyl Glycine. May contain Iron Oxides (CI 77492, CI 77489)

### **Questions or comments?**

Call toll free 1-800-933-9344 or visit [dermae.com](http://dermae.com)

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

### **PRINCIPAL DISPLAY PANEL - 4 g Container Carton**

100% VEGAN • SOY-FREE

• CRUELTY-FREE •

SPF

30

DERMA • E

ESSENTIALS

Sun Protection

Mineral Powder

BROAD SPECTRUM SPF 30

oil-free, mattifying with  
a translucent finish  
for all skin types

• DERMATOLOGIST  
RECOMMENDED •

0.14 OZ / 4 g

Sun Protection  
Mineral Powder SPF 30  
with Antioxidants



DERMA·E  
ESSENTIALS

Sun Protection  
Mineral Powder

BROAD SPECTRUM SPF 30

oil-free, mattifying with  
a translucent finish  
for all skin types

@AshDeleon



0.14 OZ / 4 g

Hello Beautiful,

I'm Ash Deleon and I'm passionate about all things beauty! My Sun Protection Non-Nano Mineral Powder SPF 30 leaves your skin naturally silky with an ultimate flawless finish.

- Protects skin from harmful UVA/UVB sun rays
- Infused with antioxidants Green Tea, Chamomile, and Vitamin E
- Helps to absorb excess oil, keeping your skin looking fresh

Easy to carry and to reapply throughout the day for all day sun protection.

XOXO  
Ash ♥

Find Ash Deleon  
on Instagram  
@ashdeleon

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

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

NDC 54108-1485-1

Distributed by DERMA E®  
Simi Valley, CA 93085, USA  
800.933.9344 • [dermae.com](http://dermae.com)  
Made in the USA of foreign and domestic components

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.

2107



# DERMA E MINERAL SUNSCREEN MINERAL

zinc oxide powder

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54108-1485
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	172.9 mg in 1 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>MATRICARIA CHAMOMILLA FLOWERING TOP OIL</b> (UNII: SA8AR2W4ER)	
<b>CAPRYLOYL GLYCINE</b> (UNII: 8TY5YO42NJ)	
<b>UNDECYLENOYL GLYCINE</b> (UNII: 4D20464K2J)	
<b>BROWN IRON OXIDE</b> (UNII: 1N032N7MFO)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54108-1485-2	1 in 1 BOX	12/01/2021	
1	NDC:54108-1485-1	4 g in 1 CONTAINER; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT		12/01/2021	

FINAL

part 532

12/01/2021

**Labeler** - derma e (148940450)

**Registrant** - Topiderm, Inc. (049121643)

Revised: 1/2023

derma e