

**DERMA E ULTRA SHEER MINERAL BODY SUNSCREEN MIST SPF 30- titanium dioxide,  
zinc oxide spray  
Topiderm 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.*

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**Derma-E Ultra Sheer Mineral Body Sunscreen Mist SPF 30**

***Drug Facts***

***Active Ingredient***

Titanium Dioxide 6%, Zinc Oxide 6%

***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 consult physician**

if irritation or rash develops.

**Keep out of reach of children.**

If product is swallowed, get medical attention or contact poison control center immediately.

***Directions***

- Apply liberally 15-minutes before sun exposure.
- Reapply: At least every two-hours. Immediately after swimming, sweating or towel drying.
- 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.
  - For children under 6-months, consult a physician.

### ***Other information***

- Protect this product from excessive heat and direct sunlight.

### ***Inactive Ingredients***

\*Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, \*Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Caprylyl/Capryl Glucoside, \*Carthamus Tinctorius (Safflower) Oil, Gluconolactone, \*Glycerin, Glyceryl Caprylate, Glyceryl Stearate Citrate, Glyceryl Undecylenate, \*Glycyrrhiza Glabra (Licorice) Extract, \*Helianthus Annuus (Sunflower) Oil, Lecithin, Leuconostoc/Radish Root Ferment Filtrate, Lonicera Caprifolium, (Honeysuckle) Extract, Lonicera Japonica (Honeysuckle) Extract, Polyhydroxystearic Acid, Populus Tremuloides Bark Extract, \*Punica Granatum (Pomegranate) Extract, Stearic Acid, \*Theobroma Cacao (Cocoa) Butter), Tocopherol (Vitamin E), Xanthan Gum. \*Certified Organic Ingredients

### ***Questions or comments?***

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

### **Package Labeling:**



# DERMA·E

## Ultra Sheer Mineral Body Sunscreen Mist

BROAD SPECTRUM SPF 30  
Non-Nano Mineral Zinc Oxide  
Vitamin E & Green Tea



- ✓ Non-Aerosol spray
- ✓ Water resistant 80 minutes
- ✓ Fast-absorbing
- ✓ Lightweight & non-greasy



6 FL OZ / 177 mL

### Good for you, good for the planet.

With ultra-sheer UVA/UVB protection, our water resistant (80 min), non-nano mineral Zinc Oxide sunscreen mist is fast-absorbing and fragrance-free. Formulated with Vitamin E, Green Tea & Pomegranate Extract, cooling Aloe, soothing Licorice & Honeysuckle Extracts, and nourishing Cocoa Butter, our environmentally-friendly, non-aerosol spray is perfect for those hard to reach places.

#### We Suggest:

- Spray 4 inches away from body.
- Do not spray directly on face or neck. Instead, use the DERMA E Sun Defense Mineral Sunscreen SPF 30 Face



#### Drug Facts

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**Warnings**  
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**\*Certified Organic Ingredients**

**Questions or comments?**  
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Made in the USA of foreign and domestic components.



1902

## DERMA E ULTRA SHEER MINERAL BODY SUNSCREEN MIST SPF 30

titanium dioxide, zinc oxide spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51326-041
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	60 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8 SF37)	ZINC CATION	60 mg in 1 mL

<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
LICORICE (UNII: 61ZBX54883)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
POPULUS TREMULOIDES BARK (UNII: 554300CEID)	
POMEGRANATE (UNII: 56687D1Z4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
COCOA (UNII: D9108TZ9KG)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	

<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:51326-041-00	177 mL in 1 CAN; Type 0: Not a Combination Product	04/10/2019	

<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352	04/10/2019	

**Labeler** - Topiderm Inc. (049121643)