

**MINERAL SUNSCREEN SPF 50- zinc oxide titanium dioxide powder**  
**Topiderm, Inc.**

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**Mineral Sunscreen**  
**SPF 50**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Zinc Oxide 24%	Sunscreen
Titanium Dioxide 22.5%	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 immediately.

**Directions**

- Apply liberally 15 minutes before sun exposure
- Reapply 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 & other sunscreen measures including:

- Limit time in the sun, especially from 10a.m.-2p.m.
- Wear long-sleeve shirts, pants, hats, & sunglasses
- Children under 6 months of age: Ask a doctor.

**Other Information**

Protect the product in this container from excessive heat and direct sun.

## **Inactive ingredients**

Mica, Silica, Caprylic/Capric Triglyceride, Lauroyl Lusine, Potassium Sorbate, Sodium Benzoate, Undecylenoyl Glycine, Capryloyl Glycine. Camellia Sinensis Polyphenols, Caffeine, Resveratrol, Tocopheryl Acetate, Carthamus Tinctorius (Safflower) Seed Oil, Camellia Sinensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Iron Oxides (CI 77489, CI 77492)

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

MINERAL POWDER

UVA/UVB

BROAD

SPECTRUM

SPF

50

SUN PROTECTION

+ OIL CONTROL

Protects against visible aging

Sets makeup and reduces shine

Translucent color blurs imperfections

BROAD SPECTRUM SPF 50

Net wt. 0.14 oz. (4 g)

MINERAL SUN PROTECTION

SPF 50

MINERAL POWDER

UVA/UVB  
BROAD  
SPECTRUM  
SPF 50

- + 100% mineral actives
- + Portable brush
- + Easy-to-apply



**Drug Facts**

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  - Children under 6 months of age: Ask a doctor.

**Other Information**

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**Inactive ingredients**

Mica, Silica, Caprylic/Capric Triglyceride, Lauroyl Lysine, Potassium Sorbate, Sodium Benzoate, Undecylenoyl Glycine, Capryloyl Glycine, Camellia Sinensis Polyphenols, Caffeine, Resveratrol, Tocopheryl Acetate, Carthamus Tinctorius (Safflower) Seed Oil, Camellia Sinensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Iron Oxides (CI 77489, CI 77492)

R0420      MADE IN U.S.A.      1205MB

**ESSENTIAL ACTIVE PROTECTION**

100% mineral powder SPF 50 is a soft and lightweight formula providing full facial sun protection with an easy to apply (and reapply!) brush application.

- UVA/UVB Broad Spectrum
- Green Tea Polyphenols, Resveratrol and Caffeine nourish and protect
- Chamomile soothes and calms
- Safflower seed oil reduces dirt and oil
- Suitable for post procedure use

**ALL IN 1 PERFORMANCE**

- Set makeup, reduce shine and blur imperfections while protecting skin against harmful UV rays.
- Portable, easy to apply brush makes it convenient and enjoyable to look perfected all day long. Reapply throughout the day as often as needed.

**SUN PROTECTION + OIL CONTROL**

Protects against visible aging  
Sets makeup and reduces shine  
Translucent color blurs imperfections

**BROAD SPECTRUM SPF 50**

Net wt. 0.14 oz. (4 g)



# MINERAL SUNSCREEN SPF 50

zinc oxide titanium dioxide powder

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51326-125
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	240 mg in 1 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	225 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>MICA</b> (UNII: V8A1AW0880)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>LAUROYL LYSINE</b> (UNII: 113171Q70B)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>CAFFEINE</b> (UNII: 3G6A5W338E)	
<b>RESVERATROL</b> (UNII: Q369O8926L)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	

## Product Characteristics

<b>Color</b>	RED	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC 51326-125			

1	NDC:51326-125-05	1 in 1 CARTON	10/14/2020	
1		4 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	10/14/2020	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Prisha Cosmetics, Inc		192609902	MANUFACTURE(51326-125)

Revised: 2/2023

Topiderm, Inc.