

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

**Mineral Sunscreen
SPF 50**

Drug Facts

Active ingredients	Purpose
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



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Other Information

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Inactive ingredients

Mica, Silica, Caprylic/Capric Triglyceride, Lauryl 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

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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 FINAL	part352	10/14/2020	

Labeler - Topiderm, Inc. (049121643)

Registrant - Topiderm, Inc. (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-125)

Revised: 3/2023

Topiderm, Inc.