

**TINTED MINERAL SUNSCREEN SPF 50- zinc oxide and titanium dioxide lotion**  
**Topiderm, Inc.**

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

***Drug Facts***

<b><i>Active ingredient</i></b>	<b><i>Purpose</i></b>
Zinc Oxide 11%	Sunscreen
Titanium Dioxide 7.5%	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.**

**When using this product** keep out of eyes, rinse with water to remove.

**Stop use if** signs of irritation or rash appear. If irritation or rash persists consult a doctor.

**Keep out of reach of children.**

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

**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 and other sunscreen measures including:

- limit time in the sun, especially from 10 a.m.-2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses

**Directions**

- Apply liberally to face and neck and spread evenly 15 minutes before sun exposure
- Re-apply after swimming, excessive perspiring, or anytime after towel drying
- Use a water resistant sunscreen if swimming or sweating
- Use on children under 6 months of age: consult a doctor.

**Inactive ingredients**

Purified Water, Dimethicone, Methyl Trimethicone, Isononyl Isononanoate, Oleth-3

Phosphate, PEG-9 Polydimethylsiloxyethyl Dimethicone, Alumina, Butylene Glycol, Octyldodecyl Neopentanoate, VP/Eicosene Copolymer, Sodium Hyaluronate, Tocopheryl Acetate, Caffeine, Polyisobutene, Iron Oxides, Sucrose, Glycerin, Silicone, Isopropyl Titanium Triisostearate, Polysorbate 20, Polyacrylate-13, Panthenol, Cetearyl Alcohol, Dicapryl Phosphate, Ceteth-20 Phosphate, PEG-8 Methyl Ether Triethoxysilane, Hydrogen Dimethicone Polyglyceryl-6 Polyricinoleate, Xanthan Gum, Sodium Hydroxide, Phenoxyethanol, Disodium EDTA.

**PRINCIPAL DISPLAY PANEL - 99 g Bottle Label**

COMPLIMENTS OF  
TOPIX  
PHARMACEUTICALS, INC

MULTI-TASKING

Mineral  
Lightly Tinted  
Antioxidant  
Sunscreen  
SPF 50+

Broad Spectrum SPF 50+  
Water Resistant 40 minutes

Net wt. 3.5 oz. (99 g)

Available  
Custom Branded  
800.445.2595  
c.service@topixpharm.com

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R0220 MADE IN U.S.A. 1203MB

Continued on back of peel panel

## Drug Facts (continued)

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## TINTED MINERAL SUNSCREEN SPF 50

zinc oxide and titanium dioxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51326-123
<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	110 mg in 1 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	75 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>METHYL TRIMETHICONE</b> (UNII: S73ZQI0GXM)	
<b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)	
<b>OLETH-3 PHOSPHATE</b> (UNII: 8Q0Z18J1VL)	
<b>PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: TYP81E471F)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)	
<b>VINYLPYRROLIDONE/EICOSENE COPOLYMER</b> (UNII: 035MV9S1C3)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CAFFEINE</b> (UNII: 3G6A5W338E)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW)</b> (UNII: 1DXE3F3OZX)	
<b>DEXPANTHENOL</b> (UNII: 1O6C93RI7Z)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>DIHEXADECYL PHOSPHATE</b> (UNII: 2V6E5WN99N)	
<b>CETETH-20 PHOSPHATE</b> (UNII: 921FTA1500)	
<b>TRIETHOXSILANE</b> (UNII: 8T460WDH89)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-123-03	99 g in 1 BOTTLE; Type 0: Not a Combination Product	11/10/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M020	11/10/2020	

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

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-123)

Revised: 4/2025

Topiderm, Inc.