

TOPIX MINERAL MATTIFYING TINTED SUNSCREEN SPF 30- zinc oxide cream **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.

Topix Mineral Mattifying Tinted Sunscreen SPF 30

Drug Facts

Active ingredient	Purpose
Zinc Oxide 16.5%	Sunscreen
Titanium Dioxide 3.2%	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 10a.m.-2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses

Directions

- Apply liberally and spread evenly by hand 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

Alumina, Ascorbic Acid, Biotin, Butylene Glycol, Butyrospermum Parkii (Shea) Butter, Camellia Sinensis Leaf (Green Tea) Polyphenols, Caprylic/Capric Triglyceride, Centella Asiatica Extract, Ceramide NS, Cyclopentasiloxane, Cyclotetrasiloxane, Dimethicone Crosspolymer, Dimethicone, Hexyl Laurate, Iron Oxides, Isododecane, Methyl Trimethicone, PEG/PPG-18/18 Dimethicone, PEG-10 Dimethicone, PEG-8 Methyl Ether Triethoxysilane, Phospholipids, Phyllanthus Emblica Fruit Extract, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polymethylsilsesquioxane, Polysilicone-11, Purified Water, Resveratrol, Silica Dimethyl Silylate, Silica, Stearic Acid, Tocopherol, Ubiquinone (Co-Enzyme Q10).

PRINCIPAL DISPLAY PANEL - 54 g Bottle Label

COMPLIMENTS OF
TOPIX
PHARMACEUTICALS, INC

MULTI-TASKING

Mineral Mattifying
Tinted Sunscreen
SPF 30

Broad Spectrum SPF 30

Net wt. 1.9 oz. (54 g)

Available
Custom Branded
800.445.2595
c.service@topixpharm.com

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Drug Facts (continued)

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• wear long-sleeve shirts, pants, hats, and sunglasses

R0721

Made in U.S.A.

1300MB

Polysilicone-11, Purified Water, Resveratrol,
Silica Dimethyl Silylate, Silica, Stearic Acid,
Tocopherol, Ubiquinone (Co-Enzyme Q10).

TOPIX MINERAL MATTIFYING TINTED SUNSCREEN SPF 30

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51326-130
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	162 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	32 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BIOTIN (UNII: 6SO6U10H04)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SHEA BUTTER (UNII: K49155WL9Y)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CENTELLA ASIATICA WHOLE (UNII: 7M867G6T1U)	
CERAMIDE NG (UNII: C04977SRJ5)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
FERROUS OXIDE (UNII: G7036X8B5H)	
ISODODECANE (UNII: A8289P68Y2)	
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
PEG-10 DIMETHICONE (220 CST) (UNII: 287GF3Y3WC)	
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)	
PHYLLANTHUS EMBLICA FRUIT (UNII: YLX4CW2576)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	

WATER (UNII: 059QF0KO0R)	
RESVERATROL (UNII: Q369O8926L)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
COENZYME Q10, (2Z)- (UNII: U705VLF0VW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-130-01	54 g in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/21/2023	

Labeler - Topiderm, Inc. (049121643)

Registrant - Topiderm, Inc. (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-130)

Revised: 2/2023

Topiderm, Inc.