TINTED MINERAL SUNSCREEN SPF 50- zinc oxide and titanium dioxide lotion
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.

Tinted Mineral Sunscreen
SPF 50

Drug Facts

Active ingredient	***Purpose***
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, Dicetyl 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

TINTED MINERAL SUNSCREEN SPF 50

zinc oxide and titanium dioxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51326-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	110 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	75 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAFFEINE (UNII: 3G6A5W338E)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
TRIETHOXYSILANE (UNII: 8T460WDH89)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EDETATE DISODIUM (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 FINAL	part352	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: 2/2023

Topiderm, Inc.