REPLENIX TINTED SUNSCREEN SPF 50- zinc oxide and octinoxate 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.

Replenix® Tinted Sunscreen
SPF 50

Drug Facts

Active ingredient	***Purpose***
Zinc Oxide 14.5%	Sunscreen
Octinoxate 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, Niacinamide, Oleth-3 Phosphate, Neopentyl Glycol Diheptanoate, Polyisobutene, Octyldodecyl Neopentanoate, Butylene Glycol, Sodium Hyaluronate, Tocopheryl Acetate, Caffeine, Dimethicone, Panthenol, Sucrose, Jojoba Esters, Lactic Acid, Glycerin, Ethylhexyl Stearate, Triethoxycaprylylsilane, Xanthan Gum, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Iron Oxides, PEG-7 Trimethylolpropane Coconut Ether, Hydroxyethyl Acrylate/Sodium Acryloydimethyl Taurate Copolymer, Phenoxyethanol, Disodium EDTA.

PRINCIPAL DISPLAY PANEL - 63 g Bottle Label

REPLENiX®
SUNSCREEN

ESSENTIAL
OIL FREE TINTED
SPF 50

14.5% Micronized Zinc Oxide
Multi-tasking tinted application
Sensitive skin friendly

BROAD SPECTRUM UVA/UVB SPF 50

Net wt. 2.22 oz. (63 g)

TOPIX PHARMACEUTICALS, INC. N. AMITYVILLE, NY 11701

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Drug Facts (continued)

Warnings (continued)

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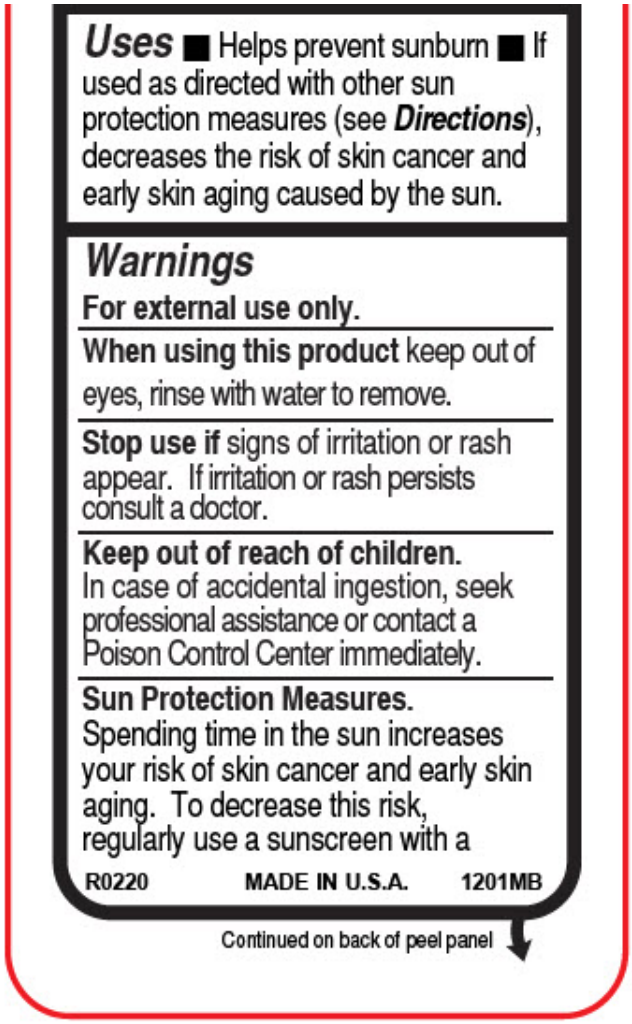

REPLENIX TINTED SUNSCREEN SPF 50

zinc oxide and octinoxate lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51326-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	145 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
NIACINAMIDE (UNII: 25X51I8RD4)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	

NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAFFEINE (UNII: 3G6A5W338E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PANTHENOL (UNII: WV9CM0O67Z)	
SUCROSE (UNII: C151H8M554)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
LACTIC ACID, DL- (UNII: 3B8D35Y7S4)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
FERROUS OXIDE (UNII: G7036X8B5H)	
PEG-7 TRIMETHYLOLPROPANE COCONUT ETHER (UNII: MVJ3AD73GG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-201-01	63 g in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/22/2022	

Labeler - Topiderm, Inc. (049121643)

Registrant - Topiderm, Inc. (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-201)

Revised: 2/2023 Topiderm, Inc.