

TINTED RESTORATIVE MOISTURIZER- zinc oxide cream
SKINERGIX LLC

DRUG FACTS

ACTIVE INGREDIENT:
Zinc Oxide 16%

PURPOSE:
Sunscreen

USES:
Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early aging caused by the sun.

WARNINGS:
For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:
• Apply liberally 15 minutes before sun exposure
• Use a water resistant product if swimming or sweating.
• Reapply at least every 2 hours
• Children under 6 months: Ask a doctor
• 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 value of 15 or higher and other sun protection measures including:
• Limit time in the sun, especially from 10 am - 2 pm
• Wear long-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS:
Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer

OTHER INFORMATION:
• Protect this product from excessive heat and direct sun
• May stain some fabrics.

MANUFACTURED FOR: 305-702-0272
Skinergix LLC. www.skinergix.com
Miami Beach FL, 33140 info@skinergix.com



SKINERGIX
AGELESS SKINCARE

BROAD SPECTRUM SPF 40
SUNSCREEN

TINTED RESTORATIVE
MOISTURIZER

with zinc oxide & ceramides

non-comedogenic
lightweight
no white cast
no shine

Net Wt. 1.75 oz / 50 g

TINTED RESTORATIVE MOISTURIZER
zinc oxide cream

Product Information

Table with 4 columns: Product Type, HUMAN OTC DRUG, Item Code (Source), NDC:85582-208(NDC:58892-208). Row 2: Route of Administration, TOPICAL.

Active Ingredient/Active Moiety

Table with 3 columns: Ingredient Name, Basis of Strength, Strength. Row 1: ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z), ZINC OXIDE, 160 mg in 1 g

Inactive Ingredients

Table with 2 columns: Ingredient Name, Strength

<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)	
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)	
<b>CI 77491</b> (UNII: 1K09F3G675)	
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>CAPRYLIC/CAPRIC TRIGLYCERIDE</b> (UNII: C9H2L21V7U)	
<b>CERAMIDE 3</b> (UNII: 4370DF050B)	
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)	
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)	
<b>CI 77499</b> (UNII: XM0M87F357)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)	
<b>CI 77492</b> (UNII: EX438O2MRT)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85582-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/01/2024	

Labeler - SKINERGIX LLC (107391863)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85582-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85582-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85582-208)