

DAILY TINTED MINERAL SPF- titanium dioxide, zinc oxide cream

Skin Restoration Aesthetics

Active Ingredients:

Titanium Dioxide 10%

Zinc Oxide 3%

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 skin 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 the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Apply liberally 15 minutes before sun exposure.
- Reapply: • After 40 minutes of swimming or sweating • Immediately after towel drying • 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:

Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Ceteareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract, Mica, Microcrystalline Wax, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, Triethanolamine, Triethoxycaprylsilane, Water

Other Information:

- Protect this product from excessive heat and direct sun
- May stain some fabrics

Warning:

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DRUG FACTS

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Daily Mineral Sunscreen
SPF 50
tinted

spf 50 broad spectrum
water resistant (40 minutes)

Net Wt. 1.8 oz / 53 g

MANUFACTURED FOR:
The Skin Restoration
San Jose, CA 95131 www.theskinrestoration.com

DAILY TINTED MINERAL SPF			
titanium dioxide, zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85296-258
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	100 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	30 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
CETEARETH-20 (UNII: YRC528SWJY)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B)	
IRON OXIDES (UNII: 1K09F3G675)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ISODODECANE (UNII: A8289P68Y2)	
MELISSA OFFICINALIS (UNII: YF70189L0N)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85296-258-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/24/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/24/2024	

Labeler - Skin Restoration Aesthetics (134407850)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85296-258)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85296-258)

Revised: 3/2025

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