

# ESSENTIAL MINERAL SUN PROTECTION- titanium dioxide, zinc oxide cream Fern Burg

**DRUG FACTS**

<b>ACTIVE INGREDIENTS:</b> Titanium Dioxide 10% Zinc Oxide 3%	<b>PURPOSE:</b> Sunscreen Sunscreen
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**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

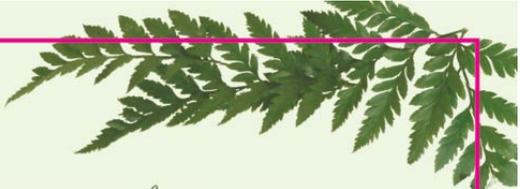
**INACTIVE INGREDIENTS:**  
Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Cetareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officialis (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

**MANUFACTURED FOR:**  
Faces by Fern | Valley Village, CA 91607  
<https://shopfacesbyfern.com/>







## Essential Mineral Sun Protection, Tinted

SPF  
50

Broad Spectrum  
Water Resistant  
(40 minutes)

- ✓ Acne-Safe
- ✓ All-Mineral Sunscreen
- ✓ Anti-Oxidants C & E
- ✓ Animal Test-Free
- ✓ Preservative Free
- ✓ Reef Friendly
- ✓ Vegan

Net Wt. 1.8 oz / 53 g

## ESSENTIAL MINERAL SUN PROTECTION

titanium dioxide, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85387-258(NDC:58892-258)
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	100 mg in 1 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	30 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
CI 77491 (UNII: 1K09F3G675)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
ISODODECANE (UNII: A8289P68Y2)	
CI 77492 (UNII: EX438O2MRT)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CI 77499 (UNII: XM0M87F357)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CETEARETH-20 (UNII: YRC528SWJY)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85387-258-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/13/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/13/2023	

**Labeler** - Fern Burg (042907660)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Custom Analytics LLC		144949372	analysis(85387-258)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fragrance Manufacturing Inc.		793406000	manufacture(85387-258)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fallien Cosmeceuticals Ltd.		958388357	relabel(85387-258)

Revised: 12/2025

Fern Burg