

# TINTED MINERAL SUNSCREEN STICK- titanium dioxide, zinc oxide stick

Hirschman, Kristina

**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:** Alumina, Aluminum Hydroxide, Aluminum Stearate, Ascorbic Acid, Ascorbyl Palmitate, C12-15 Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Ethylene Brassylate, Ethylhexyl Palmitate, Helianthus Annuus (Sunflower) Wax, Hexyldecanol, Hexyldecyl Laurate, Iron Oxide, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, Propylene Glycol Dicaprylate/Dicaprate, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oil

**Other Information:**

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

**Manufactured For:** Four Season Skin Co.  
1344 Ross Street, Wrightwood Ca 92397





**FOUR SEASON SKIN CO.**

broad spectrum  
spf 45  
water resistant  
(80 minutes)

Net Wt. 1 oz /30 g

Tinted Mineral Sunscreen Stick



**Tinted Mineral Sunscreen Stick**

**DRUG FACTS**

**Active Ingredients**  
Titanium Dioxide 4.0%, Zinc Oxide 5.5%

**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 80 minutes of swimming or sweating
- Immediately after towel drying



## TINTED MINERAL SUNSCREEN STICK

titanium dioxide, zinc oxide stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85414-220(NDC:58892-220)
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	55 mg in 1 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	40 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALUMINA</b> (UNII: LMI26O6933)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>PEG/PPG-15/15 DIMETHICONE</b> (UNII: 184IZ28A2G)	
<b>CETYL DIMETHYLBUTYL ETHER</b> (UNII: 7LAB1GXG9G)	
<b>CITRIC ACID</b> (UNII: 2968PHW8QP)	
<b>ETHYLENE BRASSYLATE</b> (UNII: 9A87HC7ROD)	
<b>HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX</b> (UNII: 42DG15CHXV)	
<b>CI 77491</b> (UNII: 1K09F3G675)	
<b>CI 77492</b> (UNII: EX438O2MRT)	

<b>CI 77499</b> (UNII: XM0M87F357)
<b>PEG-8</b> (UNII: B697894SGQ)
<b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)
<b>PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: O4446S9CRA)
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>HEXYLDECYL LAURATE</b> (UNII: 0V595C1P6M)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>CERESIN</b> (UNII: Q1LS2UJO3A)
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)
<b>ALUMINUM STEARATE</b> (UNII: U6XF9NP8HM)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>ZINGIBER OFFICINALE (GINGER) ROOT OIL</b> (UNII: SAS9Z1SVUK)
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)
<b>CETEARYL ISONONANOATE</b> (UNII: P5O01U99NI)
<b>HEXYLDECANOL</b> (UNII: 151Z7P1317)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85414-220-30	30 g in 1 CYLINDER; Type 0: Not a Combination Product	11/08/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/08/2023	

**Labeler** - Hirschman, Kristina (117585491)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85414-220)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(85414-220)

### Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85414-220)

