

# TINTED SUNSCREEN- titanium dioxide, zinc oxide cream

## Scottsdale Skin Boutique and Dermatology Plc

### DRUG FACTS

**ACTIVE INGREDIENTS:**  
Titanium Dioxide 8%  
Zinc Oxide 3.8%

**PURPOSE:**  
Sunscreen  
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
  - 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:**  
Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide (CI 77491), Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

**OTHER INFORMATION:**

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

**MANUFACTURED FOR:**  
Scottsdale Skin Boutique & Dermatology  
Scottsdale, AZ 85254  
www.ssbderm.com • (480) 998-1400



**tinted  
sunscreen+**  
broad spectrum spf 40  
water resistant (80 minutes)  
antioxidants c & e

- preservative-free
- cruelty-free
- reef-friendly

Net Wt. 1.8 oz / 53 g

<b>TINTED SUNSCREEN</b>			
titanium dioxide, zinc oxide cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85331-203(NDC:58892-203)
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	80 mg in 1 g
	<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	38 mg in 1 g
<b>Inactive Ingredients</b>			

Ingredient Name	Strength
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>CI 77491</b> (UNII: 1K09F3G675)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>CI 77492</b> (UNII: EX438O2MRT)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)	
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)	
<b>LAURYL PEG/PPG-18/18 METHICONE</b> (UNII: ZJ5S27D9NX)	
<b>ALUMINA</b> (UNII: LMI26O6933)	
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)	
<b>CI 77499</b> (UNII: XM0M87F357)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V15VM0)	
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85331-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/20/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/20/2022	

**Labeler** - Scottsdale Skin Boutique and Dermatology Pllc (098226198)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85331-203)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(85331-203)

### Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85331-203)