

**TINTED MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream**  
**MILL VALLEY DERMATOLOGY, INC.**

-----

**Active Ingredients:**

Titanium Dioxide 8%

Zinc Oxide 3.8%

**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 broken or damaged 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.

**Warnings:**

Keep out of reach of children

**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 a.m. - 2 p.m. 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
- Cleanse thoroughly at nighttime
- PA +++



TINTED MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85970-203(NDC:58892-203)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	38 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	80 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)	
<b>LAURYL PEG/PPG-18/18 METHICONE</b> (UNII: ZJ5S27D9NX)	
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)	
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)	
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)	
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ALUMINA</b> (UNII: LMI26O6933)	
<b>CI 77491</b> (UNII: 1K09F3G675)	
<b>CI 77492</b> (UNII: EX438O2MRT)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>CI 77499</b> (UNII: XM0M87F357)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85970-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/12/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/12/2020	

**Labeler -** MILL VALLEY DERMATOLOGY, INC. (057136716)

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85970-203)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85970-203)

## Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85970-203)

