

**TINTED MATTE DEFENSE SUNSCREEN PRIMER- titanium dioxide, zinc oxide cream**  
**Mint Skin Incorporated**

**DRUG FACTS**

<b>ACTIVE INGREDIENTS:</b> Titanium Dioxide 8% Zinc Oxide 3.8%	<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 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:**  
Mint Skin Studio | Greensboro, NC 27405

  
3 85533 20350 1  
[www.mintskinstudio.com](http://www.mintskinstudio.com)



**TINTED MATTE DEFENSE  
SUNSCREEN / PRIMER**

**broad spectrum SPF 40  
water resistant (80 minutes)**

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net wt. 1.8 oz / 53 g

**TINTED MATTE DEFENSE SUNSCREEN PRIMER**

titanium dioxide, zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85533-203(NDC:58892-203)
<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	38 mg in 1 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	80 mg in 1 g

## Inactive Ingredients

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85533-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/06/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/06/2021	

**Labeler** - Mint Skin Incorporated (051663637)

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85533-203)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85533-203)

## Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85533-203)