

**TINTED MINERAL MATTE CE SUNSCREEN- titanium dioxide, zinc oxide cream**  
**The Maui Medical Group, Inc**

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## Tinted Mineral Matte CE Sunscreen

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Broad Spectrum SPF 40  
Water Resistant (80 minutes)

Age Defying • Chemical Free  
Reef Friendly

MANUFACTURED FOR: Dr. Ellecia Cook | Kahului | HI | 96732



**TINTED MINERAL MATTE CE SUNSCREEN**

titanium dioxide, zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85394-203(NDC:58892-203)
<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	80 mg in 1 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	38 mg in 1 g

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85394-203-15	15 g in 1 PACKET; Type 0: Not a Combination Product	04/14/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/14/2022	

**Labeler** - The Maui Medical Group, Inc (077677102)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85394-203)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fragrance Manufacturing Inc		793406000	manufacture(85394-203)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fallien Cosmeceuticals Ltd.		958388357	relabel(85394-203)

Revised: 12/2025

The Maui Medical Group, Inc