

SHEER TINTED SUNSCREEN STICK- titanium dioxide, zinc oxide stick  
The Maui Medical Group, Inc

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DRUG FACTS (continued)

**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:

Dr. Eliece Cook  
Kahului, HI 96732  
mmgderm.com  
(808) 242 6460



Sheer Tinted  
Sunscreen Stick

Broad Spectrum SPF 45  
Water Resistant (80 minutes)

Chemical Free  
Reef Friendly

Net Wt. 1 oz. / 30g

DRUG FACTS

ACTIVE INGREDIENTS	PURPOSE
Titanium Dioxide 4.0%	Sunscreen
Zinc Oxide 5.5%	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 • **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

SHEER TINTED SUNSCREEN STICK

titanium dioxide, zinc oxide stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85394-220(NDC:58892-220)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	40 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	55 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength
ALUMINA (UNII: LMI26O6933)			
ASCORBYL PALMITATE (UNII: QN83US2B0N)			
CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)			
CITRIC ACID (UNII: 2968PHW8QP)			
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)			
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)			
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)			
CI 77491 (UNII: 1K09F3G675)			
ALUMINUM STEARATE (UNII: U6XF9NP8HM)			
ASCORBIC ACID (UNII: PQ6CK8PD0R)			

<b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)	
<b>PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: O4446S9CRA)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>ZINGIBER OFFICINALE (GINGER) ROOT OIL</b> (UNII: SAS9Z1SVUK)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>HEXYLDECANOL</b> (UNII: 151Z7P1317)	
<b>CI 77492</b> (UNII: EX438O2MRT)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CETEARYL ISONONANOATE</b> (UNII: P5O01U99NI)	
<b>PEG/PPG-15/15 DIMETHICONE</b> (UNII: 184IZ28A2G)	
<b>CI 77499</b> (UNII: XM0M87F357)	
<b>PEG-8</b> (UNII: B697894SGQ)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85394-220-30	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** - The Maui Medical Group, Inc (077677102)

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85394-220)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(85394-220)

## Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85394-220)

