

PROTECT MINERAL STICK TINTED- titanium dioxide, zinc oxide stick
Melinda Menezes, M.D., Inc.

<p>DRUG FACTS (continued)</p> <p>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</p> <p>OTHER INFORMATION: • Protect this product from excessive heat and direct sun</p>  <p>3 85314 22030 7</p> <p>MANUFACTURED FOR: Melinda Menezes, MD Inc. Lihue, HI 96766</p>	 <p>PROTECT mineral sunscreen stick</p> <p>TINTED</p> <p>broad spectrum spf 45 water resistant (80 minutes)</p> <p>net wt. 1 oz / 30 g</p>	<p>DRUG FACTS</p> <table border="1"> <tr> <th>ACTIVE INGREDIENTS</th> <th>PURPOSE</th> </tr> <tr> <td>Titanium Dioxide 4.0%</td> <td>Sunscreen</td> </tr> <tr> <td>Zinc Oxide 5.5%</td> <td>Sunscreen</td> </tr> </table> <p>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.</p> <p>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.</p> <p>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</p>	ACTIVE INGREDIENTS	PURPOSE	Titanium Dioxide 4.0%	Sunscreen	Zinc Oxide 5.5%	Sunscreen
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PROTECT MINERAL STICK TINTED			
titanium dioxide, zinc oxide stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85314-220(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
	ASCORBYL PALMITATE (UNII: QN83US2B0N)		
	CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXD9G)		
	ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)		
	CI 77492 (UNII: EX438O2MRT)		
	PEG-8 (UNII: B697894SGQ)		
	POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)		
	STEARIC ACID (UNII: 4ELV7Z65AP)		
	CETEARYL ISONONANOATE (UNII: P5O01U99NI)		
	PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)		
	POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)		

TOCOPHEROL (UNII: R0ZB2556P8)
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALUMINUM STEARATE (UNII: U6XF9NP8HM)
ALUMINA (UNII: LMI26O6933)
CITRIC ACID (UNII: 2968PHW8QP)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
HEXYLDECANOL (UNII: 151Z7P1317)
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)
CI 77491 (UNII: 1K09F3G675)
CI 77499 (UNII: XM0M87F357)
CERESIN (UNII: Q1LS2UJO3A)
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
ASCORBIC ACID (UNII: PQ6CK8PD0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85314-220-30	30 g in 1 CYLINDER; Type 0: Not a Combination Product	04/15/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/15/2025	

Labeler - Melinda Menezes, M.D., Inc. (022910406)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85314-220)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(85314-220)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85314-220)

