

NON-TINTED MINERAL STICK- titanium dioxide, zinc oxide stick
Shelley Bennett Skincare

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, 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

MANUFACTURED FOR:
Shelley Bennett Skincare
Monterey, CA 93940
www.shelleyskin.com



NON-TINTED MINERAL
SUNSCREEN STICK

Broad Spectrum SPF 45

Water Resistant (80 minutes)

Net Wt. 1 oz. / 30 g

DRUG FACTS

ACTIVE INGREDIENTS
Titanium Dioxide 4.0%
Zinc Oxide 5.5%

PURPOSE
Sunscreen
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

NON-TINTED MINERAL STICK

titanium dioxide, zinc oxide stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85326-219
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
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)			
ALUMINUM STEARATE (UNII: U6XF9NP8HM)			
CETEARYL ISONONANOATE (UNII: P5O01U99NI)			
CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)			
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TOCOPHEROL (UNII: ROZB2556P8)			
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)			
CITRIC ACID (UNII: 2968PHW8QP)			
PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)			
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)			

ASCORBIC ACID (UNII: PQ6CK8PD0R)	
PEG-8 (UNII: B697894SGQ)	
ALUMINA (UNII: LMI26O6933)	
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HEXYLDECANOL (UNII: 151Z7P1317)	
CERESIN (UNII: Q1LS2UJO3A)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85326-219-30	30 g in 1 CYLINDER; Type 0: Not a Combination Product	05/27/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/27/2024	

Labeler - Shelley Bennett Skincare (088733941)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85326-219)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85326-219)