MINERAL BASED SUNSCREEN STICK NON-TINTED- titanium dioxide, zinc oxide stick

KATHLEEN P. HUTTON, M.D., INC. A PROFESSIONAL CORPORATION

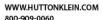
DRUG FACTS (continued)

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 Disostearate, 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: Kathleen Hutton MD Newport Beach, CA 92660







N T

Broad Spectrum

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 mintues 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

MINERAL BASED SUNSCREEN STICK NON-TINTED

titanium dioxide, zinc oxide stick

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81679-219

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE

Inactive Ingredients				
Ingredient Name	Strength			
ETHYLHEXYL PALMITATE (UNII: 2865993309)				
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)				
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)				
PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ 28A2G)				
ALUMINA (UNII: LMI26O6933)				
CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)				
CITRIC ACID (UNII: 2968PHW8QP)				
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)				
HEXYLDECANOL (UNII: 151Z7P1317)				

HEXYLDECYL LAURATE (UNII: 0V595C1P6M)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CETEARYL ISONONANOATE (UNII: P5001U99NI)	
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)	
CERESIN (UNII: Q1LS2UJO3A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PEG-8 (UNII: B697894SGQ)	
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)	
TOCOPHEROL (UNII: ROZB2556P8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	

Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date
1	NDC:81679-219- 30	30 g in 1 CYLINDER; Type 0: Not a Combination Product	07/10/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/10/2024	

Labeler - KATHLEEN P. HUTTON, M.D., INC. A PROFESSIONAL CORPORATION (792310955)

Establishment				
Name	Address	ID/FEI	Business Operations	
Fragrance Manufacturing Inc.		793406000	manufacture(81679-219)	

Establishment					
Name	Address	ID/FEI	Business Operations		
Custom Analytics LLC		144949372	analysis (81679-219)		

Revised: 4/2025 KATHLEEN P. HUTTON, M.D., INC. A PROFESSIONAL CORPORATION