

MINERAL BASED SUNSCREEN STICK 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, Iron Oxide, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Dilsostearate, 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:
 Kathleen Hutton MD
 Newport Beach, CA 92660



WWW.HUTTONKLEIN.COM
 800-909-0060



SPF 45
 Mineral Based
 Sunscreen Stick

- Free of Chemical Sunscreens
- Water-Resistant (80 Minutes)
- Broad Spectrum



Net. Wt. 1 oz./ 30 g

MINERAL BASED SUNSCREEN STICK TINTED

titanium dioxide, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81679-220(NDC:58892-220)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	55 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CI 77492 (UNII: EX438O2MRT)	
CI 77491 (UNII: 1K09F3G675)	
CI 77499 (UNII: XM0M87F357)	

CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)
ALUMINUM STEARATE (UNII: U6XF9NP8HM)
ALUMINA (UNII: LMI26O6933)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
STEARIC ACID (UNII: 4ELV7Z65AP)
PEG-8 (UNII: B697894SGQ)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
CITRIC ACID (UNII: 2968PHW8QP)
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)
HEXYLDECANOL (UNII: 151Z7P1317)
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)
CETEARYL ISONONANOATE (UNII: P5O01U99NI)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)
TOCOPHEROL (UNII: R0ZB2556P8)
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z15VUK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81679-220-30	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
Custom Analytics LLC		144949372	analysis(81679-220)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(81679-220)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(81679-220)

