

MINERAL BASED FOAM SUNSCREEN NON-TINTED- titanium dioxide, zinc oxide aerosol, foam
KATHLEEN P. HUTTON, M.D., INC. A PROFESSIONAL CORPORATION

DRUG FACTS (cont)

- 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

INACTIVE INGREDIENTS: Butyloctyl Salicylate, *Cis*-Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cellulose Gum, Ceteareth-20, Cetearyl Alcohol, Citric Acid, Disodium EDTA, Glycereth-26, Glycerin, Glyceryl Stearate, Isododecane, Isohexadecane, Methyl Methacrylate Crosspolymer, Microcrystalline Cellulose, Octyldodecyl Erucate, Octyldodecyl Neopentanoate, Poly C₁₀₋₃₀ Alkyl Acrylate, Polyhydroxystearic Acid, Polysorbate 80, Trans-1,3,3,3-Tetrafluoropropene, Triacontanyl PVP, Triethoxycaprylylsilane, Water

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun.
- May stain some fabrics.
- Store between 68° to 104° F (20° to 40° C).
- Do not store at temperatures above 120° F.

MANUFACTURED FOR:
 Kathleen Hutton MD
 Newport Beach, CA 92660

WWW.HUTTONKLEIN.COM
 800-909-0060

NDC 381679211042



SPF 30
 Non-Tinted
 Mineral Based
 Foam Sunscreen

- Free of Chemical Sunscreens
- Water-Resistant (40 Minutes)
- Unscented
- Oil and PABA Free

Net. Wt. 3.5 oz./ 100 g

MINERAL BASED FOAM SUNSCREEN NON-TINTED

titanium dioxide, zinc oxide aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81679-211(NDC:58892-211)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	30 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	100 mg in 1 g

D
 Au
 Ti
 Zi
 U
 as
 m
 th
 ag
 W
 • I
 cc
 at
 • F
 de
 as
 th
 w
 re
 m
 Co
 D
 • S
 • F
 • J
 • F

• C
 c

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID (UNII: 2968PHW8QP)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
ISODODECANE (UNII: A8289P68Y2)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
1,3,3,3-TETRAFLUOROPROPENE, (1E)- (UNII: 5I2481U0O8)	
GLYCERETH-26 (UNII: NNE56F2N14)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECYL ERUCATE (UNII: D4N66T98C2)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CELLULOSE GUM (UNII: K679OBS311)	
CETEARETH-20 (UNII: YRC528SWJY)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0KO0R)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TRIACONTANYL PVP (UNII: N0SS3Q238D)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S) (UNII: 8Z5ZAL5H3V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81679-211-04	100 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/10/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/10/2021	

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

Establishment

Name	Address	ID/FEI	Business Operations
Tri Pac, Inc.		020844956	manufacture(81679-211)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(81679-211)

Revised: 12/2025

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