

**MINERAL BASED FOAM SUNSCREEN 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:** Bismuth Oxychloride, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Capryhydroxamic Acid, Caprylyl Glycol, Cellulose Gum, Cetearyl Alcohol, Citric Acid, Disodium EDTA, Glycereth-26, Glycerin, Glyceryl Stearate, Iron Oxides, Isododecane, Isohexadecane, Methyl Methacrylate Crosspolymer, Mica, Microcrystalline Cellulose, Octyldodecyl Neopentanoate, Poly C10-30 Alkyl Acrylate, Polyhydroxystearic Acid, Polysorbate 80, Trans-1,3,3-Tetrafluoropropene, Tricontanyl PVP, Triethoxycaprylsilane, 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 381679210045



**SPF 30**  
 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 TINTED**

titanium dioxide, zinc oxide aerosol, foam

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81679-210(NDC:58892-210)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

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## Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>CI 77492</b> (UNII: EX438O2MRT)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CI 77491</b> (UNII: 1K09F3G675)	
<b>BISMUTH OXYCHLORIDE</b> (UNII: 4ZR792I587)	
<b>CETEARETH-20</b> (UNII: YRC528SWJY)	
<b>CETEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CITRIC ACID</b> (UNII: 2968PHW8QP)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S)</b> (UNII: 8Z5ZAL5H3V)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>OCTYLDODECYL ERUCATE</b> (UNII: D4N66T98C2)	
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CELLULOSE GUM</b> (UNII: K679OBS311)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>1,3,3,3-TETRAFLUOROPROPENE, (1E)-</b> (UNII: 5I2481U008)	
<b>CI 77499</b> (UNII: XM0M87F357)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>GLYCERETH-26</b> (UNII: NNE56F2N14)	
<b>GLYCERYL STEARATE</b> (UNII: 230OU9XXE4)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>TRIACONTANYL PVP</b> (UNII: N0SS3Q238D)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81679-210-04	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	

## Establishment

Name	Address	ID/FEI	Business Operations
Tri Pac, Inc.		020844956	manufacture(81679-210)

## Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(81679-210)

Revised: 12/2025

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