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

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

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: 5I2481UOO8)	
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: YRC528SWUY)	
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