

**COTZ SILKY FOAM - TINTED- titanium dioxide, zinc oxide aerosol, foam
Fallien Cosmeceuticals, LTD**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients:

Titanium Dioxide 3%

Zinc Oxide 10%

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:

- Shake well before using.
- Push nozzle up to release.
- Apply liberally 15 minutes before sun exposure.
- Reapply:
 - After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours
 - Children under 6 months: Ask a doctor
- **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 a.m.-2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses

Inactive Ingredients:

Bismuth Oxychloride, Butyloctyl Salicylate, C8-22 Alkyl Acrylates/Methacrylic Acid Crosspolymer, C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cellulose Gum, Cetareth-20, Cetearyl Alcohol, Citric Acid, Disodium EDTA, Glycereth-26, Glycerin, Glyceryl Stearate, Iron Oxides Methyl Methacrylate Crosspolymer, Mica, Microcrystalline Cellulose, Octyldodecyl Neopentanoate, Polyhydroxystearic Acid, Polymethyl Methacrylate, Polysorbate 80, Trans-1,3,3,3-Tetrafluoropropene, Triaccontanyl 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 temperature above 120° F

Manufactured Exclusively For:

CoTZ® Skincare

Norristown, PA 19403

www.cotzskincare.com

Principal Display Panel - Carton Label

CoTZ®

the HEALTHIER SUNSCREEN®

**Silky
Foam**

Tinted

**SPF
30**

**Vanishing Zinc Oxide
MINERAL SUNSCREEN**

BODY

Broad Spectrum SPF 30

Water Resistant (40 Minutes)

Net Wt. 3.5 oz/100 g



Principal Display Panel - Can Label

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- Push nozzle up to release safety tab.
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titanium dioxide, zinc oxide aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-430
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
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERETH-26 (UNII: NNE56F2N14)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
1,3,3,3-TETRAFLUOROPROPENE, (1E)- (UNII: 5I2481U008)	
TRICONTANYL POVIDONE (UNII: N0SS3Q238D)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-430-01	1 in 1 CARTON	05/16/2019	
1		100 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/29/2016	

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-430)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-430) , PACK(58892-430)

Establishment

Name	Address	ID/FEI	Business Operations
Keystone Industriess		014769301	MANUFACTURE(58892-430)

Revised: 1/2022

Fallien Cosmeceuticals, LTD