

TIZO SHEERFOAM- 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 10:00 a.m.-2:00 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses

Inactive Ingredients:

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, Methyl Methacrylate Crosspolymer, Microcrystalline Cellulose, Octyldodecyl Neopentanoate, Polyhydroxystearic Acid, Polysorbate 80, Trans-1,3,3-Tetrafluoropropene, Triacontanyl PVP, Triethoxycaprylylsilane, Water

Other Information:

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

Fallien Cosmeceuticals Ltd.
Eagleville, PA
19403
Made in USA

@tizoskin
www.tizofusion.com

PATENTED Covered by one or more of the following patents: 10,154,946; 9,561,159; 8,911,754; 8,795,696

Principal Display Panel - 1 Can Carton Label

**MINERAL
PROTECTION**

**TIZO®
SHEERFOAM™**

**NON-TINTED
SPF 30**

***Mineral Sunscreen
For Body & Face***

Titanium & Zinc Oxides

Weightless

Spreads Easily

Broad Spectrum SPF 30

Water Resistant (40 minutes)

Net Wt. 3.5 oz/100 g

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TIZO® creates all-mineral broad spectrum sunscreen protection that is exceptionally lightweight, virtually invisible on skin, and free of chemical sunscreen filters, dyes, fragrances, gluten, oils and preservatives. TIZO® offers incomparable elegance and efficacious protection against UVA and UVB radiation.

MINERAL PROTECTION

TIZO® SheerFoam™ is a patented, mineral sunscreen mousse. This unique formulation offers sheer, weightless protection while providing superb photo-protective performance. This light, foaming sunscreen dries virtually invisible on any complexion.

TIZO®

SHEERFOAM™

NON-TINTED SPF 30

TIZO® Mineral Protection helps to prevent pigmentation changes and slow the visible signs of premature skin aging associated with sun exposure. Solar radiation exposure results in dry, damaged skin with a higher risk of skin discoloration, fine lines and wrinkles as well as an increased risk of skin cancer.

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Mineral Sunscreen For Body & Face

Titanium & Zinc Oxides
Weightless
Spreads Easily

Broad Spectrum SPF 30
Water Resistant (40 minutes)

Net Wt. 3.5 oz/100 g

- Physical broad spectrum protection
- Gentle protection is suitable for post-procedure use and sensitive skin
- Photostable, will not degrade in sunlight
- FREE of chemical sunscreen filters, dyes, fragrances, oils and preservatives
- Reef-friendly

PATENTED

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8,911,754; 8,795,696



Principal Display Panel - 100g Can Label

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TIZO SHEERFOAM

titanium dioxide, zinc oxide aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-130
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
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)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
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:58892-130-01	1 in 1 CARTON	07/11/2019	
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	04/20/2012	

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-130)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-130) , PACK(58892-130)

Establishment

Name	Address	ID/FEI	Business Operations
Keystone Industries		014769301	MANUFACTURE(58892-130)

Revised: 1/2022

Fallien Cosmeceuticals, LTD