

TIZO SHEERFOAM - 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. Use caution during first application. 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 am-2 pm
- Wear long-sleeved shirts, pants, hats, and sunglasses

Inactive ingredients:

Bismuth Oxychloride, Butyloctyl Salicylate, 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, Isododecane, Isohexadecane, Methyl Methacrylate Crosspolymer, Mica, Macrocrystalline 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

Principal Display Panel - 1 Can Carton Label

TiZO®

SHEERFOAM™

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



Principal Display Panel - 100g Can Label

**MINERAL
PROTECTION**

**TIZO®
SHEERFOAM™**

**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

MINERAL
PROTECTION

TIZO[®]

SHEERFOAM[™]

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

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

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

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

TIZO SHEERFOAM - TINTED

titanium dioxide, zinc oxide aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-230
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)	
ISODODECANE (UNII: A8289P68Y2)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
Mica (UNII: V8A1AW0880)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
OCTYLDODECYL ERUCATE (UNII: D4N66T98C2)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
BEHENYL ACRYLATE POLYMER (UNII: D64PM5UT4U)	
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
	NDC 58892-230			

1	NDC:58892-230-01	1 in 1 CARTON	12/01/2022	
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(58892-230)

Establishment			
Name	Address	ID/FEI	Business Operations
Tri-Pac Inc		020844956	MANUFACTURE(58892-230)

Revised: 12/2022

Fallien Cosmeceuticals, LTD