

TIZO SHEER BOTANICALS NON-TINTED- titanium dioxide, zinc oxide cream
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 3.0%

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:

Apply liberally 15 minutes before sun exposure.

Reapply:

- After 80 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:

Butyrospermum Parkii (Shea) Butter, C₁₂₋₁₅ Alkyl Benzoate, Camellia Oleifera (Green Tea) Leaf Extract, Capric/Caprylic Triglyceride, Glyceryl Caprylate, Glyceryl Undecylenate, Melissa Officinalis (Balm Mint) Extract, Olive Oil Polyglyceryl-6 Esters, Polyglyceryl-6 Pentaoleate, Polyhydroxystearic Acid,

Propanediol, Rosemarinus Officinalis (Rosemary) Extract, Salvia Officinalis (Sage) Leaf Extract, Sclerocarya Birrea (Marula) Seed Oil, Simmondsia Chinensis (Jojoba) Esters, Sodium Chloride, Sodium Stearoyl Glutamate, Tetradecane, Tetrahexyldecyl Ascorbate, Tocopherol, Tocopheryl Acetate, Water

Other Information:

- Protect this product from excessive heat and direct sun.
- Cleanse thoroughly at nighttime.

Principal Display Panel – Carton Label

**MINERAL
PROTECTION**

TIZO®

SHEER BOTANICALS

**NON-TINTED
SPF 45**

***Plant Based
Mineral Sunscreen***

For Body & Face

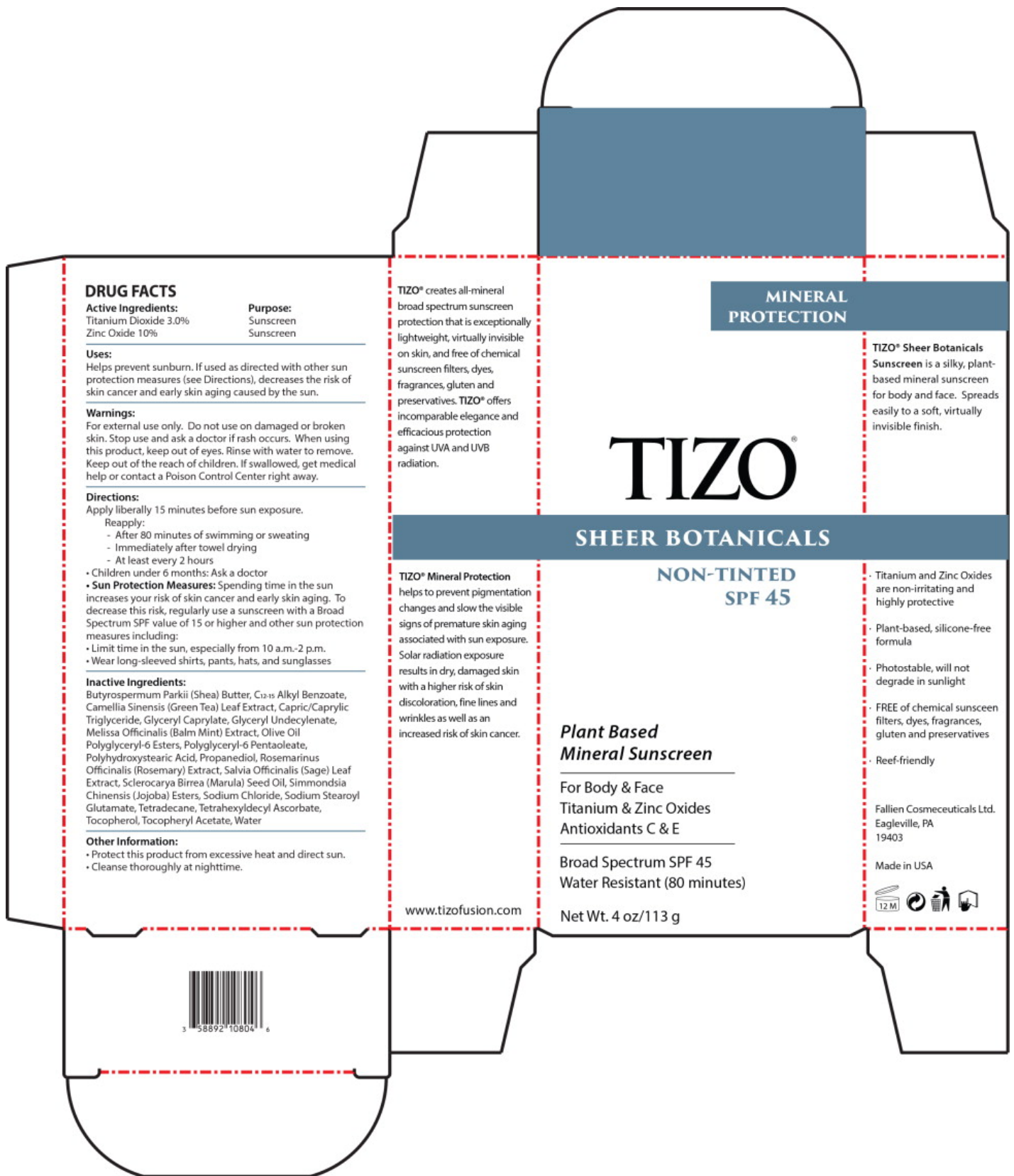
Titanium & Zinc Oxides

Antioxidants C & E

Broad Spectrum SPF 45

Water Resistant (80 minutes)

Net Wt. 4 oz/113 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 and preservatives. TIZO® offers incomparable elegance and efficacious protection against UVA and UVB radiation.

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.

TIZO®
SHEER BOTANICALS

**NON-TINTED
SPF 45**

*Plant Based
Mineral Sunscreen*

For Body & Face
Titanium & Zinc Oxides
Antioxidants C & E

Broad Spectrum SPF 45
Water Resistant (80 minutes)

Net Wt. 4 oz/113 g

TIZO® Sheer Botanicals Sunscreen is a silky, plant-based mineral sunscreen for body and face. Spreads easily to a soft, virtually invisible finish.

• Titanium and Zinc Oxides are non-irritating and highly protective

• Plant-based, silicone-free formula

• Photostable, will not degrade in sunlight

• FREE of chemical sunscreen filters, dyes, fragrances, gluten and preservatives

• Reef-friendly

Fallien Cosmeceuticals Ltd.
Eagleville, PA
19403

Made in USA



www.tizofusion.com



Principal Display Panel – Tube Label

**MINERAL
PROTECTION**

TIZO®

SHEER BOTANICALS

**NON-TINTED
SPF 45**

***Plant Based
Mineral Sunscreen***

For Body & Face







Titanium & Zinc Oxides

Antioxidants C & E

Broad Spectrum SPF 45

Water Resistant (80 minutes)

Net Wt. 4 oz/113 g

<p style="text-align: center;">MINERAL PROTECTION</p> <p style="text-align: center;">TIZO[®]</p> <p style="text-align: center;">SHEER BOTANICALS</p> <p style="text-align: center;">NON-TINTED SPF 45</p> <p><i>Plant Based Mineral Sunscreen</i></p> <p>For Body & Face Titanium & Zinc Oxides Antioxidants C & E</p> <p>Broad Spectrum SPF 45 Water Resistant (80 minutes)</p> <p>Net Wt. 4 oz/113 g</p>	<p>DRUG FACTS</p> <table border="1"><tr><td>Active Ingredients: Titanium Dioxide 3.0% Zinc Oxide 10%</td><td>Purpose: Sunscreen Sunscreen</td></tr></table> <p>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.</p> <p>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.</p> <p>Directions: Apply liberally 15 minutes before sun exposure. Reapply: - After 80 minutes of swimming or sweating - Immediately after towel drying - At least every 2 hours</p> <ul style="list-style-type: none">• 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:<ul style="list-style-type: none">• Limit time in the sun, especially from 10:00 a.m.-2:00 p.m.• Wear long-sleeved shirts, pants, hats, and sunglasses <p>Other Information:</p> <ul style="list-style-type: none">• Protect this product from excessive heat and direct sun• May stain some fabrics <p>Fallien Cosmeceuticals Ltd. Eagleville, PA 19403 Made in USA</p> <p style="text-align: right;">@tizoskin   www.tizofusion.com</p> <p style="text-align: center;">   </p>	Active Ingredients: Titanium Dioxide 3.0% Zinc Oxide 10%	Purpose: Sunscreen Sunscreen
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titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-108
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
SHEA BUTTER (UNII: K49155WL9Y)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
MELISSA OFFICINALIS (UNII: YF70189L0N)	
POLYGLYCERYL-6 STEARATE (UNII: ETY9Q81E2T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PROPANEDIOL (UNII: 5965N8W85T)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
SAGE (UNII: 065C5D077J)	
SIMMONDSIA CHINENSIS SEED WAX (UNII: 47X6Y9FJJ2)	
SCLEROCARYA BIRREA SEED OIL (UNII: WDO4TLS35F)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
1-TETRADECENE (UNII: FW23481S7S)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-108-04	1 in 1 CARTON	04/15/2019	
1		113 g in 1 TUBE; 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	04/15/2019	

Labeler - Fallien Cosmeceuticals, LTD (958388357)**Establishment**

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-108)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-108) , PACK(58892-108)

Revised: 1/2021

Fallien Cosmeceuticals, LTD