

**PROCEUTICALS PRIVATE LABEL BY TIZO TINTED FOAMING MINERAL
SUNSCREEN- titanium dioxide, zinc oxide aerosol, foam
Fallien Cosmeceuticals, Ltd**

ACTIVE INGREDIENTS:

Titanium Dioxide 3%

Zinc Oxide 10%

PURPOSE:Sunscreen

USES: Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early aging caused by the sun.

DIRECTIONS:

- Shake well before using.
- Press nozzle carefully during first use
- 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, Microcrystalline Cellulose, Octyldodecyl Erucate, Octyldodecyl Neopentanoate, Polymethyl Methacrylate, Polysorbate 80, Trans-1,3,3,3-Tetrafluoropropene, Triacontanyl PVP, Triethoxycaprylylsilane, Trimethoxycaprylylsilane, 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.

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.

Keep out of the reach of children.

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.

Apply liberally 15 minutes before sun exposure.

Principal Display Panel - 113 g Bottle Label

PROCEUTICALS

PRIVATE LABEL by TiZO

non-tinted

mineral sunscreen

20% zinc oxide

broad spectrum spf 40

water resistant (40 minutes)

net wt. 4 oz/ 113 g

Graphic-Untitled

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.
- Press nozzle carefully during first use
- 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, Microcrystalline Cellulose, Octyldodecyl Erucate, Octyldodecyl Neopentanoate, Polymethyl Methacrylate, Polysorbate 80, Trans-1,3,3,3-Tetrafluoropropene, Triaccontanyl PVP, Triethoxycaprylylsilane, Trimethoxycaprylylsilane, 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.

MANUFACTURED FOR:
City, State, Zip

NDC 58892-210-01

net wt. 3.5 oz /100 g



PROCEUTICALS
PRIVATE LABEL by TiZO

tinted foaming mineral sunscreen

broad spectrum spf 30
water resistant (40 minutes)

PROCEUTICALS PRIVATE LABEL BY TIZO TINTED FOAMING MINERAL SUNSCREEN

titanium dioxide, zinc oxide aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-210
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
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

GLYCERETH-26 (UNII: NNE56F2N14)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
BEHENYL ACRYLATE POLYMER (UNII: D64PM5UT4U)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
TRICONTANYL POVIDONE (UNII: N0SS3Q238D)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
ISODODECANE (UNII: A8289P68Y2)
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
OCTYLDODECYL ERUCATE (UNII: D4N66T98C2)
1,3,3,3-TETRAFLUOROPROPENE, (1E)- (UNII: 5I2481U008)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
MICA (UNII: V8A1AW0880)
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
WATER (UNII: 059QF0KO0R)
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)
GLYCERIN (UNII: PDC6A3C0OX)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-210-01	100 g in 1 CAN; Type 0: Not a Combination Product	07/30/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/30/2024	

Labeler - Fallien Cosmeceuticals, Ltd (958388357)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-210)

Establishment

Name	Address	ID/FEI	Business Operations
Tri-Pac Inc		020844956	manufacture(58892-210)

Revised: 7/2024

Fallien Cosmeceuticals, Ltd