

TIZO MINERAL SUN DEFENSE SPF 50- titanium dioxide, zinc oxide cream
Fallien Cosmeceuticals Ltd.

Active Ingredients:

Titanium Dioxide 10%, Zinc Oxide 3%

Purpose:

Sunscreen

Directions:

Apply liberally 15 minutes before sun exposure.

Warning:

For external use only.

Warning and Directions:

For external use only. Apply liberally 15 minutes before sun exposure.

Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Cetareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract, Mica, Microcrystalline Wax, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, Triethanolamine, Triethoxycaprylylsilane, Water

Warning:

Keep out of the reach of children.

3 X 6 MM

TIZO[®]

MINERAL SUN DEFENSE

Tinted

SPF
50

Broad Spectrum SPF 50
Water Resistant (40 Minutes)
Net. Wt. .18 Oz./5 g

DRUG FACTS

Active Ingredients:

(Purpose):

Titanium Dioxide 10%
(Sunscreen)

Zinc Oxide 3%
(Sunscreen)

Warning:

For External Use Only
Keep out of the
reach of children

Directions:

Apply liberally 15
minutes before sun
exposure

Made in USA

tizoskin.com • @tizoskin



3 58892 12805 1

Fallien Cosmeceuticals Ltd.
Eagleville, PA 19403

TIZO MINERAL SUN DEFENSE SPF 50

titanium dioxide, zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58892-128 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 100 mg in 1 g |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 30 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| MELISSA OFFICINALIS WHOLE (UNII: YF70189L0N) | |
| MICA (UNII: V8A1AW0880) | |
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY) | |
| PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U) | |
| CYCLOHEXASILOXANE (UNII: XHK3U310BA) | |
| CYCLOPENTASILOXANE (UNII: 0THT5PCI0R) | |
| BISMUTH OXYCHLORIDE (UNII: 4ZR792I587) | |
| CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) | |
| OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T) | |
| CETEARETH-20 (UNII: YRC528SWJY) | |
| IRON OXIDES (UNII: 1K09F3G675) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| ISOHEXADECANE (UNII: 918X1OUF1E) | |
| WATER (UNII: 059QF0KO0R) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| ISODODECANE (UNII: A8289P68Y2) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| TRIETHANOLAMINE (UNII: 9O3K93S3TK) | |
| ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:58892-128-05 | 5 g in 1 TUBE; Type 0: Not a Combination Product | 03/01/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 03/01/2023 | |

Labeler - Fallien Cosmeceuticals Ltd. (958388357)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

| | | | |
|------------------------------|--|-----------|------------------------|
| Fragrance Manufacturing Inc. | | 793406000 | manufacture(58892-128) |
|------------------------------|--|-----------|------------------------|

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC | | 144949372 | analysis(58892-128) |

Revised: 1/2025

Fallien Cosmeceuticals Ltd.