

**TIZO MINERAL STICK NON-TINTED SPF 45- titanium dioxide, zinc oxide stick
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 4.0%

Zinc Oxide 5.5%

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
- **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

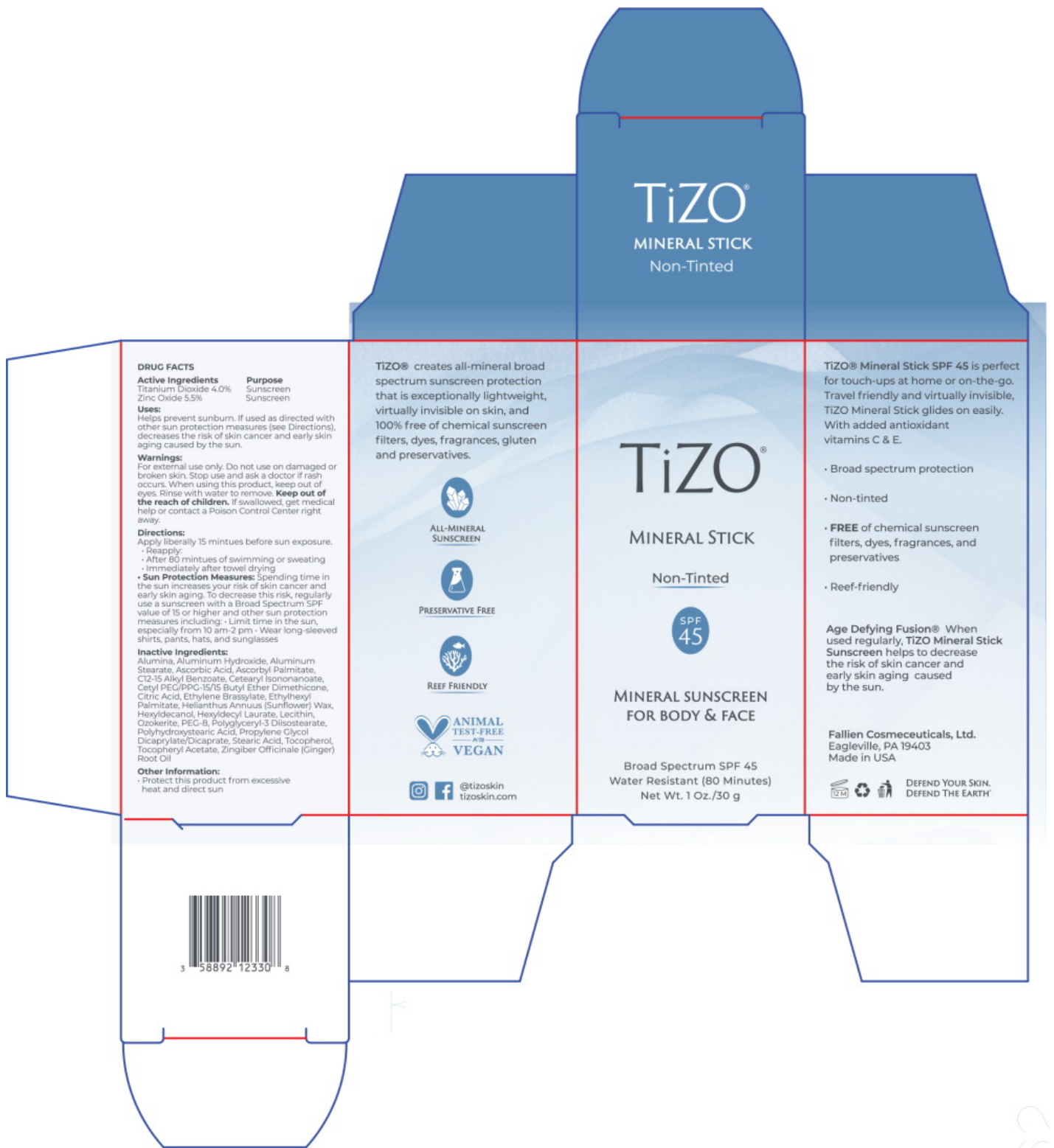
Inactive Ingredients:

Alumina, Aluminum Hydroxide, Aluminum Stearate, Ascorbic Acid, Ascorbyl Palmitate, C12-15 Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Ethylene Brassylate, Ethylhexyl Palmitate, Helianthus Annuus (Sunflower) Wax, Hexyldecanol, Hexyldecyl Laurate, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, Propylene Glycol Dicaprylate/Dicaprate, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oil

Other Information:

- Protect this product from excessive heat and direct sun

Principal Display Panel - 30 g Carton Label**TiZO®****MINERAL STICK****Non-Tinted****MINERAL SUNSCREEN
FOR BODY & FACE****Broad Spectrum SPF 45****Water Resistant (80 Minutes)****Net Wt. 1 Oz./30 g**



TIZO MINERAL STICK NON-TINTED SPF 45

titanium dioxide, zinc oxide stick

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58892-123

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP) | Titanium Dioxide | 40 mg in 1 g |
| Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z) | Zinc Oxide | 55 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| ALUMINUM STEARATE (UNII: U6XF9NP8HM) | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | |
| ASCORBYL PALMITATE (UNII: QN83US2B0N) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| CETEARYL ISONONANOATE (UNII: P5O01U99NI) | |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD) | |
| DIPROPYLENE GLYCOL CAPRYLATE (UNII: CJ981S4H3T) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV) | |
| HEXYLDECANOL (UNII: 151Z7P1317) | |
| HEXYL LAURATE (UNII: 4CG9F9W01Q) | |
| LECITHIN, SUNFLOWER (UNII: 834K0WOS5G) | |
| CERESIN (UNII: Q1LS2UJO3A) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| GINGER OIL (UNII: SAS9Z1SVUK) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:58892-123-30 | 1 in 1 CYLINDER | 07/01/2022 | |
| 1 | | 30 g in 1 CYLINDER; 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 | 07/01/2022 | |

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|----------------|---------------|----------------------------|
| Custom Analytics LLC | | 144949372 | ANALYSIS(58892-123) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------------|----------------|---------------|--|
| Fragrance Manufacturing Inc. (FMI) | | 793406000 | MANUFACTURE(58892-123) , PACK(58892-123) |

Revised: 8/2022

Fallien Cosmeceuticals, LTD