

**TIZO TINTED LIP PROTECTION SPF 45- titanium dioxide, zinc oxide stick**  
**Fallien Cosmeceuticals, LTD**

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**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
- 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 am-2:00 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, Ethylhexyl Palmitate, Flavor, Helianthus Annuus (Sunflower) Wax, Hexyldecanol, Hexyldecyl Laurate, Iron Oxide, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, Propylene Glycol Dicaprylate/Dicapryte, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oil

**Other Information:**

- Protect this product from excessive heat and direct sun
- May stain some fabrics

**Principal Display Panel - 4.5 g Carton Label****TIZO®**

TINTED LIP PROTECTION

MINERAL SUNSCREEN

SPF

45

SPF 45 Broad Spectrum

Water Resistant (80 minutes)

Net Wt. .14 oz./4.5 g.

# TiZO®

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Water Resistant (80 minutes)  
Net Wt. .14 oz/4.5 g

FA-4504

Fallien Cosmeceuticals, Ltd.  
Eagleville, PA 19403  
Made in USA



@tizoskin tizoskin.com



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# TIZO TINTED LIP PROTECTION SPF 45

titanium dioxide, zinc oxide stick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58892-339
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>ALUMINUM STEARATE</b> (UNII: U6XF9NP8HM)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CETEARYL ISONONANOATE</b> (UNII: P5O01U99NI)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>DIPROPYLENE GLYCOL CAPRYLATE</b> (UNII: CJ981S4H3T)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>CITRUS AURANTIIFOLIA FRUIT OIL</b> (UNII: 7937R189CB)	
<b>KIWI FRUIT OIL</b> (UNII: 66086CWP3Q)	
<b>HELIANTHUS ANNUUS SEED WAX</b> (UNII: 42DG15CHXV)	
<b>HEXYLDECANOL</b> (UNII: 151Z7P1317)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>GINGER OIL</b> (UNII: SAS9Z1SVUK)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:58892-339-45	1 in 1 CARTON	10/01/2022	
1		4.5 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 Drug	M020	10/01/2022	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-339)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-339) , PACK(58892-339)

Revised: 1/2025

Fallien Cosmeceuticals, LTD