

**TIZO TINTED LIP PROTECTION 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
- 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<sup>®</sup>

## TINTED LIP PROTECTION MINERAL SUNSCREEN

SPF  
45

SPF 45 Broad Spectrum  
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



**DRUG FACTS**  
**Active Ingredients**  
Titanium Dioxide 4.0%  
Zinc Oxide 5.5%  
**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 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, Hexyldecyl, Hexyldecyl Laurate, Iron Oxide, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Disteostearate, Polyhydroxystearic Acid, Propylene Glycol Dicaprylate/Dicaprynyl Stearate, 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

# 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
---	-----------	---------------------	----------------------	--------------------

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 not final	part352	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: 10/2022

Fallien Cosmeceuticals, LTD