

**COTZ LIP BALM- 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.*

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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 a.m.-2:00 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses

### **Inactive Ingredients:**

Alumina, Aluminum Hydroxide, Aluminum Stearate, Asorbic Acid, Ascorbyl Palmitate, C<sub>12-15</sub> Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Dipropylene Glycol Dicaprylate-Caprates, Ethylhexyl Palmitate, Flavor, Helianthus Annuus (Sunflower) Seed Wax, Hexyldecanol, Hexyldecyl Laurate, Iron Oxide, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, 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

Not tested on animals

### **Principal Display Panel - 4.5 g Carton Label**

**CoTZ<sup>®</sup>**  
the HEALTHIER  
SUNSCREEN<sup>®</sup>

#### **Lip Balm**

Lightly Tinted

**100% Free of**  
Chemical Sunscreens,  
Lanolin, Gluten

PROTECT & MOISTURIZE

SPF 45 Broad Spectrum • Water Resistant (80 Minutes)

Net Wt. .14 oz/4.5 g



# Lip Balm

Lightly Tinted

**100% Free of**  
Chemical Sunscreens,  
Lanolin, Gluten

**PROTECT & MOISTURIZE**

SPF  
**45**

SPF 45 Broad Spectrum • Water Resistant (80 Minutes)  
Net Wt. .14 oz/4.5 g



Manufactured Exclusively For:  
**CōTZ® Skincare**  
Norristown, PA 19403  
www.cotzskincare.com



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**Inactive Ingredients:**  
Alumina, Aluminum Hydroxide, Aluminum Stearate, Ascorbyl Palmitate, Cetyl PEG-15/15 Butyl Ether, Citrus Alkyl Benzozate, Cetearyl Isononanoate, Cetyl PEG-PPG-15/15 Butyl Ether, Dimethicone, Citric Acid, Dipropylene Glycol Dicaprylate-Caprate, Ethylhexyl Palmitate, Flavor, Helianthus Annuus (Sunflower) Seed Wax, Hexyldecyl Laurate, Polyhydroxystearate Iron Oxide, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3-Diisostearate, Polyhydroxystearate Acid, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oil

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# COTZ LIP BALM

titanium dioxide, zinc oxide stick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58892-124
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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

<b>Ingredient Name</b>	<b>Strength</b>
<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: B6978945GQ)	
<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

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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1	NDC:58892-124-45	1 in 1 CARTON	05/01/2021	
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	04/15/2019	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-124)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-124) , PACK(58892-124)

Revised: 5/2021

Fallien Cosmeceuticals, LTD