

**COTZ SENSITIVE SPF 40 SUNSCREEN - zinc oxide lotion**  
**Fallien Cosmeceuticals, LTD.**

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**DRUG FACTS**

**Active Ingredients:**

Zinc Oxide 20%

**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 40 minutes of swimming or sweating
  - Immediately after towel drying
  - At least every two 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 a.m.-2 p.m.
  - Wear long-sleeved shirts, pants, hats, and sunglasses

**Inactive Ingredients:**

C<sub>12-15</sub> Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexydecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

**Other Information:**

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

**Manufactured Exclusively For:**

CoTZ<sup>®</sup> Skincare  
Norrstown, PA 19403

[www.cotzskincare.com](http://www.cotzskincare.com)

**Principal Display Panel - CoTZ Sensitive Tube Label**

**CoTZ<sup>®</sup>**

the HEALTHIER  
SUNSCREEN<sup>®</sup>

**Sensitive**

Non-Tinted

SPF

**40**

**Gentle Zinc Oxide**

MINERAL SUNSCREEN

FACE & BODY

Broad Spectrum SPF 40

Water Resistant (40 minutes)

Net Wt. 3.5 oz/100 g



## Principal Display Panel - CoTZ Sensitive Carton Label

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www.cotzskincare.com

CōTZ<sup>®</sup> The Healthier Sunscreen works by reflecting harmful UVA-UVB rays before they can penetrate the skin.



**MINERAL SUNSCREEN**

**100% FREE OF:**

Chemical Sunscreens,  
Oils, Preservatives, Fragrances,  
Parabens, Gluten, Phthalates

CōTZ<sup>®</sup> Sensitive SPF 40 Mineral Sunscreen protects and soothes sensitive or easily irritated skin. Gentle, non-tinted cream blends translucent, leaving a soft, sheer finish. 20% Zinc Oxide is Dermatologist Recommended for even the most sensitive skin.

- Non-tinted
- Moisturizing
- Non-irritating
- Helps prevent signs of aging



**Sensitive**

Non-Tinted

SPF  
**40**

**Gentle Zinc Oxide  
MINERAL SUNSCREEN**

**FACE & BODY**

Broad Spectrum SPF 40  
Water Resistant (40 minutes)  
Net Wt. 3.5 oz/100 g



**REEF FRIENDLY**



**WATER RESISTANT**



**NO ANIMAL TESTING**



**PRESERVATIVE FREE**



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# COTZ SENSITIVE SPF 40 SUNSCREEN

zinc oxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58892-418
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	200 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>Alkyl (C12-15) Benzoate</b> (UNII: A9EJ3J61HQ)	
<b>Caprylhydroxamic Acid</b> (UNII: UPY805K99W)	
<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)	
<b>Cetyl PEG/PPG-10/1 Dimethicone (HLB 5)</b> (UNII: 035JKJ76MT)	
<b>Cyclomethicone 6</b> (UNII: XHK3U310BA)	
<b>Cyclomethicone 5</b> (UNII: 0THT5PCI0R)	
<b>Dimethicone 100</b> (UNII: RO266O364U)	
<b>Dimethicone/Diene Dimethicone Crosspolymer</b> (UNII: RSA9I561OK)	
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)	
<b>Methicone (20 cst)</b> (UNII: 6777U11MKT)	
<b>Microcrystalline Wax</b> (UNII: XOF597Q3KY)	
<b>PEG-10 Dimethicone (600 cst)</b> (UNII: 8PR7V1SVM0)	
<b>PEG-30 Dipolyhydroxystearate</b> (UNII: 9713Q0S7FO)	
<b>Polyglyceryl-4 Isostearate</b> (UNII: 820DPX33S7)	
<b>Polyhydroxystearic Acid (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>Polysorbate 20</b> (UNII: 7T1F30V5YH)	
<b>Sodium Chloride</b> (UNII: 451W47IQ8X)	
<b>Stearyl Dimethicone (400 MPA.S AT 50C)</b> (UNII: R327X197HY)	
<b>Tetrahexyldecyl Ascorbate</b> (UNII: 9LBV3F07AZ)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	
<b>Trolamine</b> (UNII: 9O3K93S3TK)	
<b>Triethoxycaprylylsilane</b> (UNII: LDC331P08E)	
<b>Water</b> (UNII: 059QF0K00R)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:58892-418-01	1 in 1 CARTON	03/30/2012	
1		100 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	03/30/2012	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-418)

## Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging		809172885	MANUFACTURE(58892-418)

Revised: 3/2025

Fallien Cosmeceuticals, LTD.