

**COTZ SPF 58 SUNSCREEN - titanium dioxide, zinc oxide cream**  
**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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**FALLENE CoTZ®**

**DRUG FACTS**

**Active Ingredients**

Titanium Dioxide 10%

Zinc Oxide 3%

**Purpose**

Sunscreen

Sunscreen

**Uses:** Helps prevent sunburn

- Retains SPF up to 40 minutes of water immersion or perspiring

**Warnings:** For external use only

- Avoid contact with eyes. In case of eye contact, flush eyes with water thoroughly
- Do not use if sensitive to ingredients • Discontinue use if irritation occurs. Consult a doctor or healthcare professional if irritation persists
- For use on children less than 6 months of age, consult a doctor.
- Keep this and all medicines out of reach of children
- If swallowed, get medical help or contact a Poison Control Center

**Directions:** Apply generously and uniformly to all exposed skin areas before exposure to sunlight

- Continue to rub in until fading occurs, especially in hair bearing areas
- Reapply as needed and after washing, swimming, towel drying, or sweating for maximum protection.

**Other Information** Sun Alert: limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun. May stain some fabric.

**Inactive Ingredients**

Acrylates C10-30 Alkyl

Acrylates Crosspolymer,

Butylene Glycol, Butyloctyl

Salicylate, Butylparaben,

Capric/Caprylic Triglyceride,

Cetearyl Alcohol, Cetearyl

Glucoside, Cyclomethicone,

Dimethicone, EDTA,

Ethylhexyl Hydroxystearate  
Benzoate, Glyceryl Stearate,  
Iron Oxides, Isobutylparaben,  
Isopropylparaben,  
Melissa Officinalis (Balm  
Mint) Extract, Octyldodecyl  
Neopentanoate, PEG-100  
Stearate, Phenoxyethanol,  
Retinyl Palmitate,  
Simethicone, Sorbitan  
Laurate, Styrene/Acrylates  
Copolymer, Talc, Tocopherol,  
Tocopheryl Acetate,  
Tricontanyl PVP, Water,  
Xanthan Gum

#### **UVA - Same Everyday**

UVA radiation, unlike UVB, is consistently the same all day long, all month long and all year long. UVA rays present almost the same damaging effects to the skin in December at 9 am, as they do in July at 4 pm. UVA radiation is consistently damaging, and in fact, enters deeper into the skin than UVB. Since UVA damage is cumulative and penetrates through glass, everyone requires daily, year round protection.

- **Extra gentle - no chemical sunscreen filters**
- **Dries clear**
- **Oil & PABA free**
- **Fragrance free**

**Manufactured exclusively for:**  
**Fallien**, West Norriton, PA 19403  
**[www.totalblock.com](http://www.totalblock.com)**

**Made in USA**

#### **Principal Display Panel**

**Principal Display Panel – Carton Label**

**NDC 58892-910-87**

**Dermatologist Recommended for Sensitive Skin**

**FALLENE CoTZ®**

**Contains Only Titanium & Zinc®**

**WATER-RESISTANT SUN PROTECTION**

**UVA-UVB SPF 58**

**Net Wt. 2.5 Oz./ 70 g**



NDC 58892-910-87

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## Dermatologist Recommended for Sensitive Skin



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### DRUG FACTS ——— Cont.

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Cetearyl Alcohol, Cetearyl  
Glucoside, Cyclomethicone,  
Dimethicone, EDTA,  
Ethylhexyl Hydroxystearate  
Benzoate, Glyceryl Stearate,  
Iron Oxides, Isobutylpara-  
ben, Isopropylparaben,  
Melissa Officinalis (Balm  
Mint) Extract, Octyldodecyl  
Neopentanoate, PEG-100  
Stearate, Phenoxyethanol,  
Retinyl Palmitate,  
Simethicone, Sorbitan  
Laurate, Styrene/Acrylates  
Copolymer, Talc, Tocopherol,  
Tocopheryl Acetate,  
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# COTZ SPF 58 SUNSCREEN

titanium dioxide, zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58892-910
<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	100 mg in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	30 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	
<b>Butylparaben</b> (UNII: 3QPI1U3FV8)	
<b>Medium-Chain Triglycerides</b> (UNII: C9H2L21V7U)	
<b>Carbomer Copolymer Type B</b> (UNII: 1G56KV7BUJ)	
<b>Cyclomethicone</b> (UNII: NMQ347994Z)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>Ferric Oxide Yellow</b> (UNII: EX438O2MRT)	
<b>Ferrosoferric Oxide</b> (UNII: XM0M87F357)	
<b>Isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>Isopropylparaben</b> (UNII: A6EOX47QK0)	
<b>Lemon Balm Oil</b> (UNII: MJ76269K9S)	
<b>Octyldodecyl Neopentanoate</b> (UNII: X8725R883T)	
<b>Polyoxyl 100 Stearate</b> (UNII: YD01N1999R)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Vitamin A Palmitate</b> (UNII: 1D1K0N0VVC)	
<b>Sorbitan Monolaurate</b> (UNII: 6W9PS8B71J)	
<b>Talc</b> (UNII: 7SEV7J4R1U)	
<b>Alpha-Tocopherol</b> (UNII: H4N855PNZ1)	
<b>Alpha-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-910-87	1 in 1 CARTON		

1	70 g in 1 TUBE		
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352	01/02/2004	

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

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Process Technologies & Packaging		809172885	MANUFACTURE, PACK

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Custom Analytics LLC		144949372	ANALYSIS

Revised: 8/2010

Fallien Cosmeceuticals, LTD.