

**SOLAR PROTECTION FORMULA SPF 65 SUNSCREEN - octinoxate, octocrylene, oxybenzone, titanium dioxide, zinc oxide lotion**  
**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 :**

Octinoxate 6%  
Octocrylene 7%  
Oxybenzone 4%  
Titanium Dioxide 4%  
Zinc Oxide 5%

**Purpose**

Sunscreen  
Sunscreen  
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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.

**SHAKE WELL BEFORE USING**

**Other Information:**

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

**Directions:**

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant product if swimming or sweating.
- Reapply 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 p.m.
  - Wear long-sleeved shirts, pants, hats, and sunglasses

**Inactive Ingredients:**

Acrylates/Octylacrylamide Copolymer, Aluminum Starch Octenylsuccinate, Ascorbyl Palmitate, 5-Bromo-5-Nitro-1, 3-Dioxane, Beta-Carotene, Butylparaben, C12-15 Alkyl Benzoate, Cetearyl Alcohol, Cetearyl Glucoside, Dimethicone, Disodium EDTA, Iron Oxides, Isobutylparaben, Isopropylparaben, Linoleamidopropyl Dimethylamine, Octyldodecyl Neopentanoate, Phenoxyethanol, Pinus Pinaster Bark Extract, Polysorbate 20, Propylene Glycol, Selenium Yeast Extract, Simethicone, Sorbitan Laurate, Talc, Tocopherol, Tocopheryl Acetate, Triethoxycaprylylsilane, Water

**Solar Protection Formula combines Titanium Dioxide, Zinc Oxide, and Iron Oxide to form a complete wall of reflection against UVA/UVB damage.**

**Manufactured exclusively for  
Fallien Ltd., West Norriton, PA  
Made in USA**

**Principal Display Panel – 2 oz Carton Label**

NDC 58892-265-59

**SOLAR**

**PROTECTION**

**FORMULA®**

**Oil Free**

**Non-comedogenic**

**SPF 65**

**Broad Spectrum**

**UVA/UVB**

2 Fl. Oz. / 58.8ml

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**Solar Protection Formula  
SPF 65 Non-Comedogenic**

- Titanium Dioxide, and Zinc Oxide for mineral protection
- Three organic chemical sunscreen filters
- Contains multiple antioxidants, vitamins C, E, and Pine Bark Extract
- No dyes, fragrances, oils or PABA
- Complete full spectrum UVB/UVA protection

**Everyone requires daily,  
year round UVA protection**

- UVA radiation is consistently the same all day and all year long
- The effects of UVA damage are cumulative
- UVA radiation is responsible for deep skin damage that results in skin aging, such as wrinkling
- Titanium Dioxide and Zinc Oxide helps to assure full spectrum UVA/UVB protection.

Oil & PABA Free  
Fragrance Free  
Dries Clear



**Oil Free  
Non-comedogenic**

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Made in USA

**SPF 65  
Broad Spectrum  
UVA/UVB**

2 Fl. Oz./ 58.8ml

**Solar Protection Formula  
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Oxide, and Iron Oxide to form a  
complete wall of reflection  
against UVA/UVB damage.**



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octinoxate, octocrylene, oxybenzone, titanium dioxide, zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58892-265
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	60 mg in 1 mL
<b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	70 mg in 1 mL
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	40 mg in 1 mL
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	40 mg in 1 mL
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	50 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Alkyl (C12-15) Benzoate</b> (UNII: A9EJ3J61HQ)	
<b>Aluminum Starch Octenylsuccinate</b> (UNII: I9PJ0O6294)	
<b>Ascorbyl Palmitate</b> (UNII: QN83US2B0N)	
<b>5-Bromo-5-Nitro-1,3-Dioxane</b> (UNII: U184I9QBNM)	
<b>.Beta.-Carotene</b> (UNII: 01YAE03M7J)	
<b>Butylparaben</b> (UNII: 3QPI1U3FV8)	
<b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)	
<b>Cetearyl Glucoside</b> (UNII: 09FUA47KNA)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)	
<b>Ferric Oxide Red</b> (UNII: 1K09F3G675)	
<b>Isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>Isopropylparaben</b> (UNII: A6EOX47QK0)	
<b>Linoleamidopropyl Dimethylamine</b> (UNII: W142CF4WLF)	
<b>Octyldodecyl Neopentanoate</b> (UNII: X8725R883T)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Maritime Pine</b> (UNII: 50JZ5Z98QY)	
<b>Polysorbate 20</b> (UNII: 7T1F30V5YH)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Sorbitan Monolaurate</b> (UNII: 6W9PS8B71J)	
<b>Talc</b> (UNII: 7SEV7J4R1U)	
<b>Tocopherol</b> (UNII: R0ZB2556P8)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	
<b>Triethoxycaprylsilane</b> (UNII: LDC331P08E)	
<b>Water</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-265-59	1 in 1 CARTON		

1	58.8 mL in 1 BOTTLE		
<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>
Custom Analytics LLC		144949372	ANALYSIS(58892-265)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Process Technologies & Packaging		809172885	MANUFACTURE(58892-265)

Revised: 12/2012

Fallien Cosmeceuticals, LTD.