

SOLAR PROTECTION FORMULA SPF 60 TINTED CONCEALER - (BEIGE) SUNSCREEN
- octinoxate, octocrylene, oxybenzone, titanium dioxide, zinc oxide lotion
SOLAR PROTECTION FORMULA SPF 60 TINTED CONCEALER - (HONEY) SUNSCREEN
- octinoxate, octocrylene, oxybenzone, titanium dioxide, zinc oxide lotion
SOLAR PROTECTION FORMULA SPF 60 TINTED CONCEALER - (BLUSH) 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.

DRUG FACTS

Active Ingredients :

Octinoxate 6%
Octocrylene 7%
Oxybenzone 4%
Titanium Dioxide 10%
Zinc Oxide 3.4%

Purpose

Sunscreen
Sunscreen
Sunscreen
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, Caramel, Beta-Carotene, Butylparaben, C12-15 Alkyl Benzoate, Cetearyl Alcohol, Cetearyl Glucoside, Disodium EDTA, Iron Oxides, Isobutylparaben, Isopropylparaben, Linoleamidopropyl Dimethylamine, Methylparaben, Octyldodecyl Neopentanoate, Phenoxyethanol, Pinus Pinaster Bark Extract, Polysorbate 20, Propylene Glycol, Simethicone, Sorbitan Laurate, Talc, Tocopherol, Tocopheryl Acetate, Triethoxycaprylylsilane, Water

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

Solar Protection Formula offers the most complete protection from UVB/UVA available, and is essential for the medically light sensitive and for those concerned with the damaging effects of the sun.

Principal Display Panel – Beige Carton Label**SOLAR****PROTECTION****FORMULA®****TINTED****CONCEALER****SPF 60****Broad Spectrum****UVA/UVB**

2 Fl.Oz./59 ml

DRUG FACTS

Active Ingredients:	Purpose
Octinoxate 6%	Sunscreen
Octocrylene 7%	Sunscreen
Oxybenzone 4%	Sunscreen
Titanium Dioxide 10%	Sunscreen
Zinc Oxide 3.4%	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

- Beige 15
- Honey 6
- Blush 9

Other Information:

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

**Solar Protection Formula
SPF 60 Tinted Concealer**

- Excellent individually customizable make-up
- Superb camouflage, able to match individual skin tones
- 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
& Fragrance Free**

Individually Customizable,
includes Light and Dark
Control Tubes



**Tinted
Concealer**

**SPF 60
Broad Spectrum
UVA/UVB**

2 Fl. Oz./ 59 ml

DRUG FACTS

- 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, Caramel, Beta-Carotene, Butylparaben, C12-15 Alkyl Benzoate, Cetearyl Alcohol, Cetearyl Glucoside, Disodium EDTA, Iron Oxides, Isobutylparaben, Isopropylparaben, Linoleamidopropyl Dimethylamine, Methylparaben, Octyldodecyl Neopentanoate, Phenoxyethanol, Pinus Pinaster Bark Extract, Polysorbate 20, Propylene Glycol, Simethicone, Sorbitan Laurate, Talc, Tocopherol, Tocopheryl Acetate, Triethoxycaprylsilane, Water

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Made in USA

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81499

Principal Display Panel – Honey Carton Label

**SOLAR
PROTECTION
FORMULA®
TINTED
CONCEALER
SPF 60
Broad Spectrum
UVA/UVB
2 Fl.Oz./59 ml**

DRUG FACTS

Active Ingredients:	Purpose
Octinoxate 6%	Sunscreen
Octocrylene 7%	Sunscreen
Oxybenzone 4%	Sunscreen
Titanium Dioxide 10%	Sunscreen
Zinc Oxide 3.4%	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

- Beige 15
- Honey 6
- Blush 9

Other Information:

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

**Solar Protection Formula
SPF 60 Tinted Concealer**

- Excellent individually customizable make-up
- Superb camouflage, able to match individual skin tones
- 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
& Fragrance Free**

Individually Customizable,
includes Light and Dark
Control Tubes



**Tinted
Concealer**

**SPF 60
Broad Spectrum
UVA/UVB**

2 Fl. Oz./ 59 ml

DRUG FACTS

- 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, Caramel, Beta-Carotene, Butylparaben, C12-15 Alkyl Benzoate, Cetearyl Alcohol, Cetearyl Glucoside, Disodium EDTA, Iron Oxides, Isobutylparaben, Isopropylparaben, Linoleamidopropyl Dimethylamine, Methylparaben, Octyldodecyl Neopentanoate, Phenoxyethanol, Pinus Pinaster Bark Extract, Polysorbate 20, Propylene Glycol, Simethicone, Sorbitan Laurate, Talc, Tocopherol, Tocopheryl Acetate, Triethoxycaprylsilane, Water

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

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81499

Principal Display Panel – Blush Carton Label

**SOLAR
PROTECTION
FORMULA®
TINTED
CONCEALER
SPF 60
Broad Spectrum
UVA/UVB
2 Fl.Oz./59 ml**

DRUG FACTS

Active Ingredients:	Purpose
Octinoxate 6%	Sunscreen
Octocrylene 7%	Sunscreen
Oxybenzone 4%	Sunscreen
Titanium Dioxide 10%	Sunscreen
Zinc Oxide 3.4%	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

- Beige 15
- Honey 6
- Blush 9

Other Information:

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

**Solar Protection Formula
SPF 60 Tinted Concealer**

- Excellent individually customizable make-up
- Superb camouflage, able to match individual skin tones
- 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
& Fragrance Free**

Individually Customizable,
includes Light and Dark
Control Tubes



**Tinted
Concealer**

**SPF 60
Broad Spectrum
UVA/UVB**

2 Fl. Oz./ 59 ml

DRUG FACTS

- 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, Caramel, Beta-Carotene, Butylparaben, C12-15 Alkyl Benzoate, Cetearyl Alcohol, Cetearyl Glucoside, Disodium EDTA, Iron Oxides, Isobutylparaben, Isopropylparaben, Linoleamidopropyl Dimethylamine, Methylparaben, Octyldodecyl Neopentanoate, Phenoxyethanol, Pinus Pinaster Bark Extract, Polysorbate 20, Propylene Glycol, Simethicone, Sorbitan Laurate, Talc, Tocopherol, Tocopheryl Acetate, Triethoxycaprylsilane, Water

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

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81499

SUNSCREEN

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-721
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	69 mg in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	81 mg in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	46 mg in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	115 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	39 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Aluminum Starch Octenylsuccinate (UNII: I9PJ0O6294)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	
.BETA.-Carotene (UNII: 01YAE03M7J)	
Butylparaben (UNII: 3QP1U3FV8)	
Caramel (UNII: T9D99G2B1R)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
Dimethicone (UNII: 92RU3N3Y1O)	
Edetate Disodium (UNII: 7FLD91C86K)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferrosulfate (UNII: XM0M87F357)	
Isobutylparaben (UNII: 0QQJ25X58G)	
Isopropylparaben (UNII: A6EOX47QK0)	
Linoleamidopropyl Dimethylamine (UNII: W142CF4WLF)	
Octyldodecyl Neopentanoate (UNII: X8725R883T)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Maritime Pine (UNII: 50JZ5Z98QY)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sorbitan Monolaurate (UNII: 6W9PS8B71J)	
Talc (UNII: 7SEV7J4R1U)	
Tocopherol (UNII: R0ZB2556P8)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-721-65	1 in 1 CARTON		
1		59 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/1994	

SOLAR PROTECTION FORMULA SPF 60 TINTED CONCEALER - (HONEY) SUNSCREEN

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-722
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	69 mg in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	81 mg in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	46 mg in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	115 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	39 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Aluminum Starch Octenylsuccinate (UNII: I9PJ0O6294)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	
.BETA.-Carotene (UNII: 01YAE03M7J)	
Butylparaben (UNII: 3QP11U3FV8)	
Caramel (UNII: T9D99G2B1R)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
Dimethicone (UNII: 92RU3N3Y1O)	
Edetate Disodium (UNII: 7FLD91C86K)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferrosoferric Oxide (UNII: XM0M87F357)	
Isobutylparaben (UNII: 0QQJ25X58G)	
Isopropylparaben (UNII: A6EOX47QK0)	
Linoleamidopropyl Dimethylamine (UNII: W142CF4WLF)	

Octyldodecyl Neopentanoate (UNII: X8725R883T)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Maritime Pine (UNII: 50JZ5Z98QY)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sorbitan Monolaurate (UNII: 6W9PS8B71J)	
Talc (UNII: 7SEV7J4R1U)	
Tocopherol (UNII: R0ZB2556P8)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-722-65	1 in 1 CARTON		
1		59 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/1994	

SOLAR PROTECTION FORMULA SPF 60 TINTED CONCEALER - (BLUSH) SUNSCREEN

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-723
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	69 mg in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	81 mg in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	46 mg in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	115 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	39 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Aluminum Starch Octenylsuccinate (UNII: I9PJ0O6294)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	

.BETA.-Carotene (UNII: 01YAE03M7J)
Butylparaben (UNII: 3QP1U3FV8)
Caramel (UNII: T9D99G2B1R)
Cetostearyl Alcohol (UNII: 2DMT128M1S)
Cetearyl Glucoside (UNII: 09FUA47KNA)
Dimethicone (UNII: 92RU3N3Y1O)
Edetate Disodium (UNII: 7FLD91C86K)
Ferric Oxide Red (UNII: 1K09F3G675)
Ferric Oxide Yellow (UNII: EX438O2MRT)
Ferrosulfate (UNII: XM0M87F357)
Isobutylparaben (UNII: 0QQJ25X58G)
Isopropylparaben (UNII: A6EOX47QK0)
Linoleamidopropyl Dimethylamine (UNII: W142CF4WLF)
Octyldodecyl Neopentanoate (UNII: X8725R883T)
Phenoxyethanol (UNII: HIE492ZZ3T)
Maritime Pine (UNII: 50JZ5Z98QY)
Polyorbate 20 (UNII: 7T1F30V5YH)
Propylene Glycol (UNII: 6DC9Q167V3)
Sorbitan Monolaurate (UNII: 6W9PS8B71J)
Talc (UNII: 7SEV7J4R1U)
Tocopherol (UNII: R0ZB2556P8)
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)
Triethoxycaprylsilane (UNII: LDC331P08E)
Water (UNII: 059QF0K00R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-723-65	1 in 1 CARTON		
1		59 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/1994	

Labeler - Fallien Cosmeceuticals, LTD. (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-721, 58892-722, 58892-723)

Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging		809172885	MANUFACTURE(58892-721, 58892-722, 58892-723)

