

COTZ PURE SPF 30 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.

DRUG FACTS

Active Ingredients:

Titanium Dioxide 4.1%

Zinc Oxide 8.4%

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

Inactive Ingredients:

Brassica Campestris/Aleurites Fordii Oil Copolymer¹ (from rapeseed and aleurites oils), Butyrospermum Parkii (Shea) Butter¹ (shea tree extract), Camellia Oleifera Leaf Extract¹ (Japanese green tea), Capric/Caprylic Triglyceride^{1,2,3}(from coconut), Cellulose Gum¹(from plant), Cetearyl Alcohol^{1,2,3}(from coconut/ palm), Cetearyl Glucoside^{1,2,3}(from coconut/palm and glucose sugar), Citric Acid (from citrus fruit), Glyceryl Caprylate^{1,2}(from coconut), Glyceryl Undecylenate^{1,2}(from castor bean and coconut glycerin), Iron Oxide¹ (CI 77491) (natural mineral), Melissa Officinalis (Balm Mint) Extract¹ (natural herb), Microcrystalline Cellulose¹ (from wood pulp), Polyhydroxystearic Acid²(from castor plant), Rosmarinus Officinalis (Rosemary) Extract¹ (natural herb), Salvia Officinalis (Sage) Leaf Extract¹ (natural herb), Simmondsia Chinensis (Jojoba) Esters^{1,2}(from natural plant) Sodium Stearoyl Glutamate^{1,2,3}(from coconut and amino acid), Sorbitan Oleate Decylglucoside Crosspolymer⁴(from sugar and plant derived oleic acid), Xanthan Gum¹(from plant sugar), Water

Other Information:

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

* All ingredients approved by one or more of these leading organizations: 1. Natural Products Association, 2. EcoCert, 3 NSF International, 4. Green Star Rated

Principal Display Panel – SPF 30 85g Carton Label

DERMATOLOGIST RECOMMENDED

CoTZ®

PURE

The Healthier Sunscreen

0%

Synthetic Ingredients

Preservatives

Chemical Sunscreens

Balanced Mineral Complex™ Helps Prevent
Heat Build-Up in Skin, which Can
Damage the Dermis

Broad
Spectrum
SPF 30

Silky Soft & Gentle
Water Resistant
(40 minutes)

Net Wt. 3.5 oz/85.0 g

CōTZ[®]
PURE
 The Healthier Sunscreen

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CōTZ PURE is a 100% natural mineral sunscreen, containing:

0% Synthetic Ingredients,
 0% Preservatives,
 0% Chemical Sunscreens,
 0% Oils,
 0% Fragrances,
 0% Parabens,
 0% PABA

CōTZ Balanced Mineral Complex™ helps prevent heat build-up in the skin, which can damage the dermis. CōTZ also helps prevent pre-mature skin aging (lines, wrinkles, sagging, age spots), uneven skin tone and other serious problems.

CōTZ sits invisibly on top of skin and functions like thousands of mirrors to deflect UVA/UVB rays before the rays can penetrate the skin.

CōTZ™ is 100% Free of chemical sunscreen ingredients, here's why:
 • Chemical sunscreens absorb UVA/UVB rays into the skin and transform the rays into heat, which can damage the dermis.

Made in U.S.A.

CōTZ[®]
PURE

The Healthier Sunscreen

0% Synthetic Ingredients
Preservatives
Chemical Sunscreens

Balanced Mineral Complex™ Helps Prevent Heat Build-Up in the Skin, which Can Damage the Dermis

Silky Soft & Gentle
 Water Resistant
 (40 Minutes)

Net Wt. 3.0 oz/85.0 g

Broad Spectrum
SPF 30

CōTZ PURE for healthier skin:

- 100% Free of Synthetic Ingredients, Preservatives, Chemical Sunscreens, Oils, Fragrances, Parabens, PABA, Gluten, Phthalates
- Does not irritate or sting
- Contains #1 and #2 rated sunscreen ingredients
- SPF 30 exceeds the level recommended by Skin Cancer Experts
- Provides broad spectrum UVA/UVB protection
- Photosable, will not breakdown when exposed to sunlight

CōTZ PURE blends to match skin tone

- Leaves skin silky, soft & smooth
- Non-Shiny, Non-Greasy
- Weightless
- Gentle for all skin types

Not tested on animals

Manufactured exclusively for CōTZ™ Skincare West Norriton, PA 19403
www.cotzskincare.com



COTZ PURE SPF 30 SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-600
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	41 mg in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	84 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Shea Butter (UNII: K49155WL9Y)	
Camellia Oleifera Leaf (UNII: 5077EL0C60)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Carboxymethylcellulose Sodium (UNII: K679OBS311)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Glyceryl Caprylate (UNII: TM2TZD4G4A)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Melissa Officinalis (UNII: YF70189L0N)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Polyhydroxystearic Acid (2300 MW) (UNII: YXH47AOU0F)	
Rosemary (UNII: IJ67X351P9)	
Sage (UNII: 065C5D077J)	
Sodium Stearoyl Glutamate (UNII: 65A9F4P024)	
Xanthan Gum (UNII: TTV12P4NEE)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-600-01	1 in 1 CARTON		
1		85 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/14/2012	

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

Name	Address	ID/FEI	Business Operations
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Custom Analytics LLC		144949372	ANALYSIS(58892-600)
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Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging		809172885	MANUFACTURE(58892-600) , PACK(58892-600)

Revised: 12/2012

Fallien Cosmeceuticals, LTD.