COTZ PLUS SPF 58 SUNSCREEN - titanium dioxide and 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 10%

Zinc Oxide 3%

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:

Acrylates C₁₀₋₃₀ Alkyl Acrylates Crosspolymer, Butylene Glycol, Butyloctyl Salicylate, Butylparaben, Capric/Caprylic Triglyceride, Cetearyl Alcohol, Cetearyl Glucoside, Cyclomethicone, Dimethicone, Ethylhexyl Hydroxystearate Benzoate, Glyceryl Stearate, Iron Oxides, Isobutylparaben, Isopropylparaben, Melissa Officinalis (Balm Mint) Leaf Extract, Octyldodecyl Neopentanoate, PEG-100 Stearate, Phenoxyethanol, Retinyl Palmitate, Simethicone, Sorbitan Laurate, Styrene/Acrylates Copolymer, Talc, Tocopherol, Tocopheryl Acetate, Tricontanyl PVP, Trisodium EDTA, Water, Xanthan Gum

Other Information:

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

Principal Display Panel – 2.5 oz Carton Label DERMATOLOGIST RECOMMENDED

CoTZ®

PLUS

The Healthier Sunscreen TM

Balanced Mineral ComplexTM

#1 Rated UV Protection*

Will Not Irritate or Sting

Helps Prevent Heat Build-Up in Skin which can Damage the Dermis

100% Free of:

Chemical Sunscreens & Oils

SPF 58 Broad

Spectrum

UVA-UVB

Blends

Translucent

Water

Resistant

(40 minutes)

Net Wt. 2.5 oz/70.0 g

DERMATOLOGIST RECOMMENDED

CoTZ® PLUS SPF 58 with Balanced Mineral Complex helps prevent heat build-up in the skin, which can damage the dermis. CoTZ helps prevent pre-mature skin aging (fine lines, wrinkles, sagging, age spots), uneven skin tone and other serious problems.

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

The Healthier Sunscreen

Balanced Mineral Complex #1 Rated UV Protection* Will Not Irritate or Sting

Helps Prevent Heat Build-Up in Skin which can Damage the Dermis

100% Free of:

Chemical Sunscreens & Oils

UVA-UVB rays into the skin and transform the rays into heat, which can damage Blends the dermis. Translucent Water

CöTZ° is 100% Free of

ingredients, here's why:

· Chemical sunscreens absorb

chemical sunscreen

Made in U.S.A.

SPF 58 Broad UVA-UVB

Net Wt. 2.5 oz/70.0 g

Resistant

(40 minutes)

Spectrum

CoTZ* PLUS SPF 58 for maximum protection & healthier skin: DRUG FACTS

• 100% Free of Chemical Sunscreens, Oils, Fragrand PABA, Gluten, Phthalates Zinc Oxide 3%

- · Will not irritate or sting Gentle for all skin types
- SPF 58 exceeds the level recommended by Skin Cancer experts
- **UVA-UVB** protection
- Photostable, will not breakdown when exposed to sunlight
- · Blends translucent
- Non-greasy
- · Water Resistant (40 Minutes)

*Contains #1 and #2 rated sun protection ingredients for

UVA-UVB rays

Not tested on animals

Manufactured exclusively for CoTZ° Skincare West Norriton, PA 19403 www.cotzskincare.com

Active Ingredients: Titanium Dioxide 10% Purpose Sunscreen Sunscreen

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:

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Inactive Ingredients:

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COTZ PLUS SPF 58 SUNSCREEN

titanium dioxide, zinc oxide cream

| Product Information | | | |
|-------------------------|----------------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG LABEL | Item Code (Source) | NDC:58892-070 |
| Route of Administration | TOPICAL | DEA Schedule | |

| Active Ingredient/Active Moiety | | | |
|-------------------------------------|-------------------|---------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| Titanium Dioxide (Titanium Dioxide) | Titanium Dioxide | 100 mg in 1 g | |
| Zinc Oxide (Zinc Oxide) | Zinc Oxide | 30 mg in 1 g | |

| Ingredient Name | Strength |
|---|----------|
| Butylene Glycol | |
| Butylparaben | |
| Medium-Chain Triglycerides | |
| Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked) | |
| Cetostearyl Alcohol | |
| Cetearyl Glucoside | |
| Cyclomethicone | |
| Dimethicone | |
| Edetate Trisodium | |
| Glyceryl Monostearate | |
| Ferric Oxide Yellow | |
| Ferrosoferric Oxide | |
| Isobutylparaben | |
| Isopropylparaben | |
| Melissa Officinalis Leaf | |
| Octyldodecyl Neopentanoate | |
| PEG-100 Stearate | |
| Phenoxyethanol | |
| Vitamin A Palmitate | |
| Sorbitan Monolaurate | |
| Talc | |
| Tocopherol | |
| AlphaTocopherol Acetate | |
| Tricontanyl Povidone (4 Tricontanyl Branches/Repeat) | |
| Water | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:58892-070-58 | 1 in 1 CARTON | | |
| 1 | | 70 g in 1 TUBE | | |
| | | | | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part352 | 0 1/0 3/20 12 | |
| | | | |

$\pmb{Labeler -} \ \, \mathsf{Fallien} \ \, \mathsf{Cosmeceuticals, LTD.} \ \, (958388357)$

| Establishment | | | |
|----------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Custom Analytics LLC | | 144949372 | ANALYSIS(58892-070) |

| Establishment | | | |
|----------------------------------|---------|-----------|---|
| Name | Address | ID/FEI | Business Operations |
| Process Technologies & Packaging | | 809172885 | MANUFACTURE(58892-070), PACK(58892-070) |

Revised: 1/2013 Fallien Cosmeceuticals, LTD.