

COTZ KIDS PURE BOTANICALS- 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 3.0%

Zinc Oxide 10%

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 80 minutes of swimming or sweating
- Immediately after towel drying
- At least every two 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:

Butyrospermum Parkii (Shea) Butter (Shea Tree Extract), C₁₂₋₁₅ Alkyl Benzoate (from Cranberries & Coconut), Camellia Sinensis (Green Tea) Leaf Extract, Capric/Caprylic Triglyceride (From Coconut), Glyceryl Caprylate (From Coconut), Glyceryl Undecylenate (From Castor Bean & Coconut), Melissa

Officinalis (Balm Mint) Extract (Natural Herb), Olive Oil Polyglyceryl-6 Esters (From Glycerin & Olive Oil), Polyglyceryl-6 Pentaoleate (From Glycerin & Olive Oil), Polyhydroxystearic Acid (From Castor Plant), Propanediol (From Corn), Rosmarinus Officinalis (Rosemary) Extract (Natural Herb), Salvia Officinalis (Sage) Leaf Extract (Natural Herb), Sclerocarya Birrea (Marula) Seed Oil (Tree Fruit Extract), Simmondsia Chinensis (Jojoba) Esters (From Natural Plant), Sodium Chloride (Natural Mineral), Sodium Stearoyl Glutamate (From Coconut & Amino Acid), Tetradecane (Derived from Vegetable Oil), Tetrahexyldecyl Ascorbate (From Mixed Citrus and Palm Oil), Tocopherol (From Mixed Fruit & Seed Extracts), Tocopheryl Acetate (From Mixed Fruit & Seed Extracts), Water

Other Information:

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

Manufactured Exclusively For:

CōTZ[®] Skincare
Norristown, PA 19403

www.cotzskincare.com

Principal Display Panel – Carton Label

CoTZ[®]
the HEALTHIER
SUNSCREEN[®]

Kids

Pure Botanicals

Non-Tinted

SPF

45

Plant Based

Mineral Sunscreen

For 6+ Months

Broad Spectrum SPF 45

Water Resistant (80 Minutes)

Net Wt. 4 oz/113 g

CōTZ
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SUNSCREEN®

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CōTZ® The Healthier Sunscreen works by reflecting harmful UVA-UVB rays before they can penetrate the skin.



MINERAL SUNSCREEN

100% FREE OF:

Chemical Sunscreens, Preservatives, Fragrances, Parabens, Gluten, Phthalates

CōTZ® Kids Pure Botanicals SPF 45 provides mineral sunscreen protection in a unique, plant-based formula that is naturally soft and gentle as well as highly protective.

- Non-tinted
- Plant and mineral based
- Non-irritating
- Easy to apply



Kids Pure Botanicals

Non-Tinted

SPF
45

Plant Based
MINERAL SUNSCREEN

For 6+ Months

Broad Spectrum SPF 45
Water Resistant (80 minutes)

Net Wt. 4 oz/113 g



REEF FRIENDLY



WATER RESISTANT



NO ANIMAL TESTING



PRESERVATIVE FREE



GLUTEN FREE



3 58892 60304 6

Principal Display Panel – Tube Label

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Non Printing Area



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Non Printing Area

COTZ KIDS PURE BOTANICALS

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-603	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)		Titanium Dioxide	30 mg in 1 g	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)		Zinc Oxide	100 mg in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
SHEA BUTTER (UNII: K49155WL9Y)				
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)				
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)				
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)				
MELISSA OFFICINALIS (UNII: YF70189L0N)				
POLYGLYCERYL-6 STEARATE (UNII: ETY9Q81E2T)				
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)				
PROPANEDIOL (UNII: 5965N8W85T)				
ROSEMARY OIL (UNII: 8LGU7VM393)				
SAGE (UNII: 065C5D077J)				
SIMMONDSIA CHINENSIS SEED WAX (UNII: 47X6Y9FJJ2)				
SCLEROCARYA BIRREA SEED OIL (UNII: WDO4TLS35F)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)				
1-TETRADECENE (UNII: FW23481S7S)				
TOCOPHEROL (UNII: R0ZB2556P8)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-603-04	1 in 1 CARTON	04/15/2019	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	04/15/2019		

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-603)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-603) , PACK(58892-603)

Revised: 1/2021

Fallien Cosmeceuticals, LTD