

COTZ KIDS MINERAL SUN STICK- titanium dioxide, zinc oxide stick
Fallien Cosmeceuticals, LTD

Active Ingredients:

Titanium Dioxide 4% Zinc Oxide 5.5%

Purpose

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 2 hours - Children under 6 months: Ask a doctor.

Inactive Ingredients:

Alumina, Aluminum Hydroxide, Aluminum Stearate, Ascorbic Acid, Ascorbyl Palmitate, C12-15 Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Ethylene Brassylate, Ethylhexyl Palmitate, Helianthus Annuus (Sunflower) Wax, Hexyldecanol, Hexyldecyl Laurate, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, Propylene Glycol Dicaprylate/Dicaprate, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oil

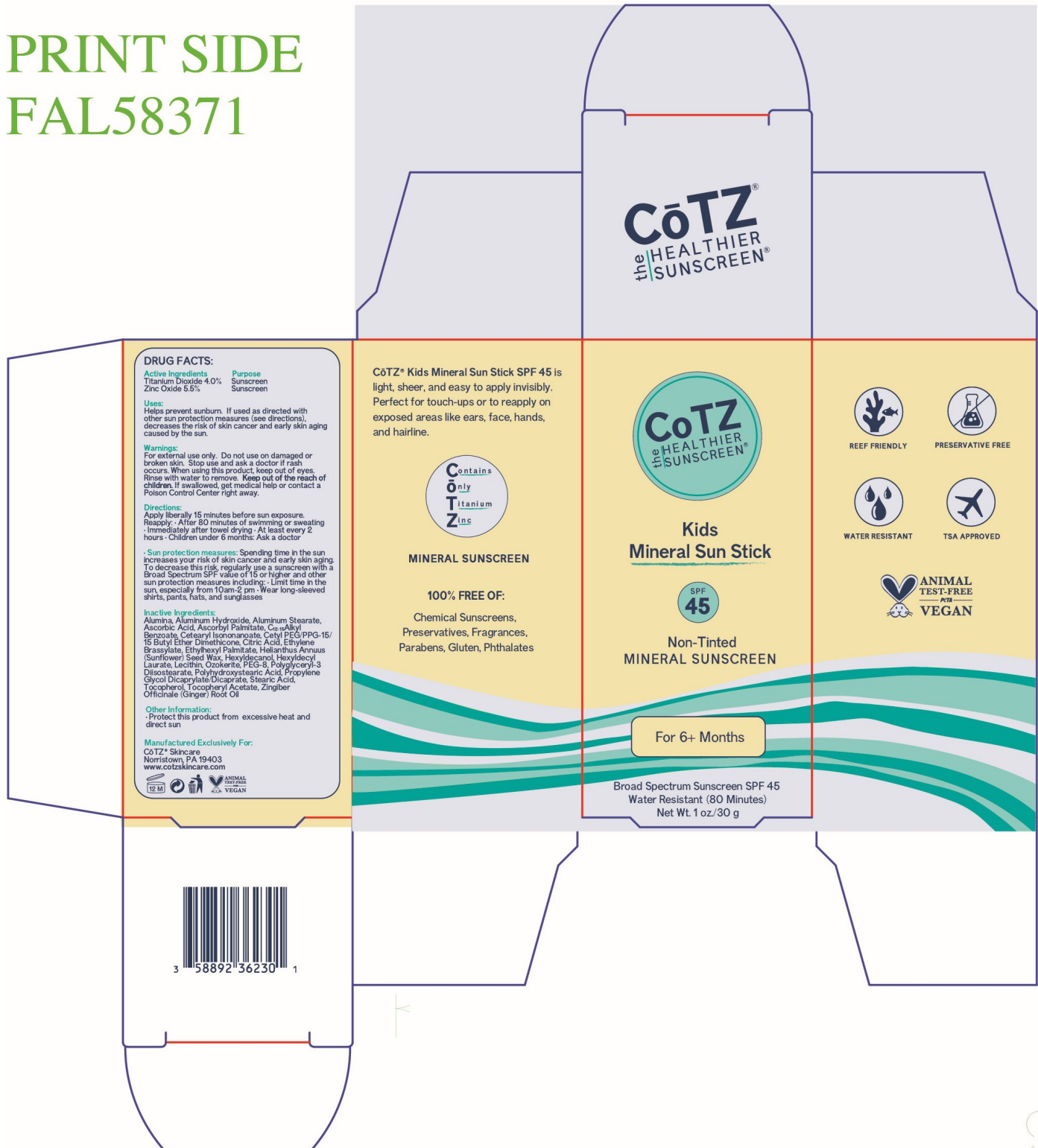
Other Information:

Protect this product from excessive heat and direct sun.

Warning:

Keep out of the reach of children.

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COTZ KIDS MINERAL SUN STICK

titanium dioxide, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-362
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	55 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
HEXYLDECANOL (UNII: 151Z7P1317)	
PEG-8 (UNII: B697894SGQ)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)	
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)	
PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CERESIN (UNII: Q1LS2UJO3A)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	
CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)	
ALUMINA (UNII: LMI26O6933)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CITRIC ACID (UNII: 2968PHW8QP)	
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-362-30	1 in 1 CARTON	03/03/2025	
1		30 g in 1 CYLINDER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC Monograph Drug	M020	03/03/2025	
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Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(58892-362)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-362)

Revised: 3/2025

Fallien Cosmeceuticals, LTD