FRUIT OF THE EARTH SUN TOWN CITY BABY AND KIDS MINERAL SPF 50 SUNSCREEN- titanium dioxide, zinc oxide lotion Fruit Of The Earth, Inc.

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.

Fruit of the Earth Sun Town City Baby and Kids Mineral SPF 50 Lotion Sunscreen

Active ingredients

Titanium Dioxide 3.0% Zinc Oxide 15.0%

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.

When using this product

• keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

rash occurs.

Keep out of reach of children

If product is swallowed, get medical help or contact a Poison Control 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 of age: 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

Other information

- protect the product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

Inactive ingredients

Water, Caprylic/Capric Triglyceride, Neopentyl Glycol Diheptanoate, Butyloctyl Salicylate, Glyceryl Stearate, Glycerin, Olive Oil Polyglyceryl-6 Esters, C30-38 Olefin/Isopropyl Maleate/MA Copolymer, Phenoxyethanol, Polyglyceryl-6 Pentaoleate, Stearyl/Octyldodecyl Citrate Crosspolymer, VP/Hexadecene Copolymer, Magnesium Sulfate, Silica, Simmondsia Chinensis (Jojoba) Seed Oil, Fragrance, Ethylhexylglycerin, Aloe Barbadensis Leaf Juice, Avena Sativa (Oat) Kernel Extract, Tocopherol, Sodium Hydroxide.

Label



BROAD SPECTRUM SPF 50 LOTION SUNSCREEN

- FRAGRANCE FREE
- HYPOALLERGENIC .
- PARABEN & PHTHALATE FREE'■
- WATER RESISTANT (80 MINUTES) #
 - NO OXYBENZONE III OR OCTINOXATE



Drug Facts

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Questions or comments? Call 1-800-527-7731

* No parabens separately added to preserve this product.

Fruit of the Earth, Inc. 3325 W. Trinity Blvd. Grand Prairie, TX 75050

www.fote.com





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titanium dioxide, zinc oxide lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62217-241

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 mL		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	150 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
JOJOBA OIL (UNII: 724GKU717M)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
STEARYL/OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: PN88NW0KPK)	
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
OAT (UNII: Z 6J799EAJK)	
MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
OLIVE OIL POLYGLYCERYL-6 ESTERS (UNII: 4KDO9AFM9I)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-241- 13	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2022	

Marketing In	Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	M020	02/08/2022			

Labeler - Fruit Of The Earth, Inc. (079559467)

Revised: 2/2023 Fruit Of The Earth, Inc.