

FRUIT OF THE EARTH SUN TOWN CITY- spf 50 lotion sunscreen 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 SPF 50 Lotion Sunscreen

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 4.5%, Octocrylene 8.0%

Purpose

Sunscreen

Uses

• helps prevent sunburn • if used as directed with other sun protectino 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 • if rash occurs.

Keep out of 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 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.,.
 - wear long-sleeve 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, polyester-7, neopentyl glycol diheptanoate, glycerin, aluminum starch octenylsuccinate, styrene/acrylates copolymer, silica, phenoxyethanol, isododecane, arachidyl alcohol, beeswax, ethylhexylglycerin, acrylates/C10-30 alkyl acrylate crosspolymer, behenyl alcohol, tocopherol (vitamin E), arachidyl glucoside, glyceryl stearate, PEG-100 stearate, potassium hydroxide, disodium EDTA, sodium ascorbyl phosphate, fragrance

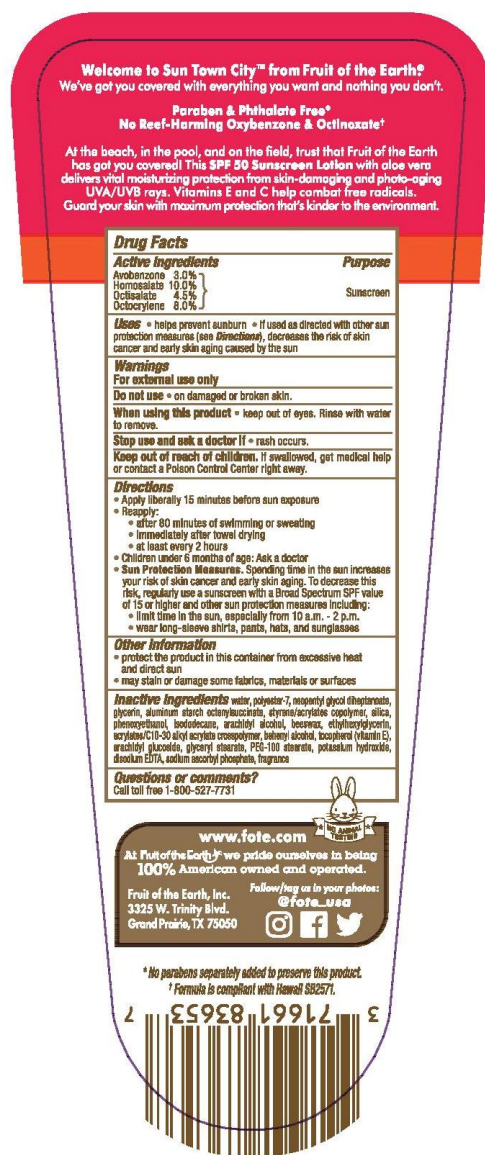
Questions or comments?

Call toll free 1-800-527-7731

Fruit of the Earth Sun Town City SPF 50 Lotion Sunscreen

8.0 FL OZ (237 mL)

NDC 62217-305-11



FRUIT OF THE EARTH SUN TOWN CITY

spf 50 lotion sunscreen lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-305	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	30 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)		HOMOSALATE	100 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)		OCTISALATE	45 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	80 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYESTER-7 (UNII: 0841698D2F)				
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)				
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
ISODODECANE (UNII: A8289P68Y2)				
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)				
DOCOSANOL (UNII: 9G1OE216XY)				
TOCOPHEROL (UNII: R0ZB2556P8)				
YELLOW WAX (UNII: 2ZA36H0S2V)				
ARACHIDYL GLUCOSIDE (UNII: 6JVVW35JOOJ)				
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
PEG-100 STEARATE (UNII: YD01N1999R)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-305-11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/10/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part352	02/10/2020	

Labeler - Fruit of the Earth, Inc. (079559467)

Registrant - Fruit of the Earth Research Laboratories, Inc. (008193515)

Establishment

Name	Address	ID/FEI	Business Operations
Fruit of the Earth, Inc.		079559467	manufacture(62217-305)

Revised: 2/2020

Fruit of the Earth, Inc.