

**FRUIT OF THE EARTH SUN TOWN CITY DARK TANNING SPF 8 SUNSCREEN-
avobenzone, octisalate, octocrylene 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 Dark Tanning SPF 8 Lotion Sunscreen

☐ Active ingredients

Avobenzone 1.5%, Octisalate 5.0%, Octocrylene 6.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

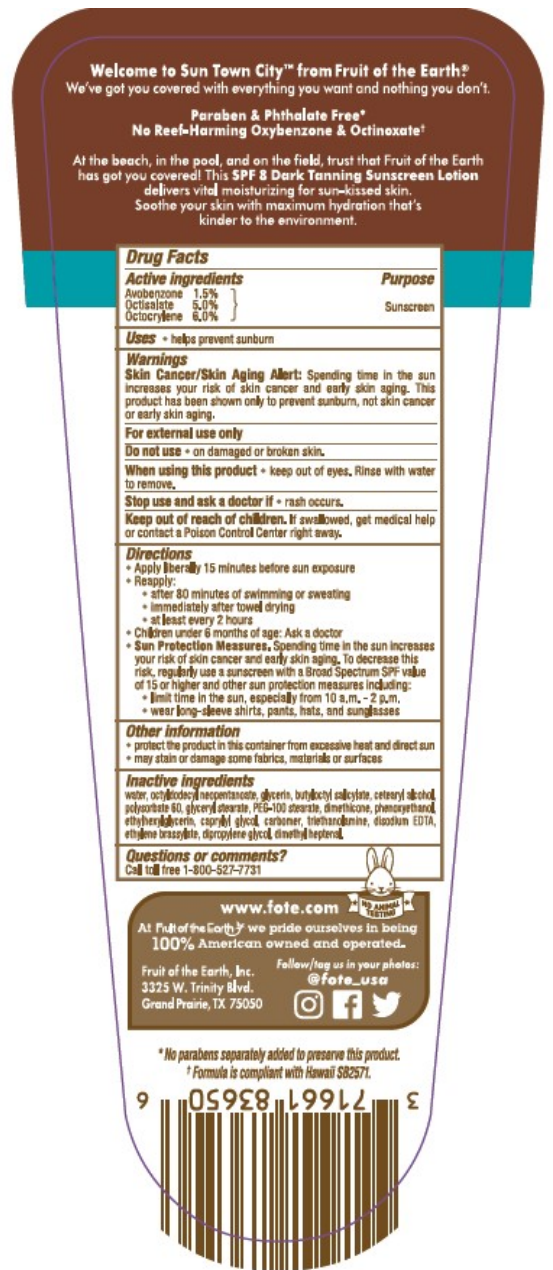
- Apply liberally 15 minutes before sun exposure
- Reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
 - Children under 6 months of age: Ask a doctor
 - **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer 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.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, octyldodecyl neopentanoate, glycerin, butyloctyl salicylate, cetearyl alcohol, polysorbate 60, glyceryl stearate, PEG-100 stearate, dimethicone, phenoxyethanol, ethylhexylglycerin, caprylyl glycol, carbomer, triethanolamine, disodium EDTA, ethylene brassylate, dipropylene glycol, dimethyl heptenal.



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-072
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	15 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TROLAMINE (UNII: 9O3K93S3TK)	
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
2,6-DIMETHYL-5-HEPTENAL (UNII: Z331YX9EL9)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
PEG-100 STEARATE (UNII: YD01N1999R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-072-11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/09/2019	

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

Revised: 7/2021

Fruit of the Earth, Inc.