

FRUIT OF THE EARTH SUN TOWN CITY BABY SPF 50 SUNSCREEN- avobenzone, homosalate, 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 Baby SPF 50 Lotion Sunscreen

Active ingredients

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 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 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, 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



3 71661 83643 8

Welcome to Sun Town City™ from Fruit of the Earth®
We've got you covered with everything you want and nothing you don't.

Drug Facts	
Active Ingredients	Purpose
Avobenzone 3.0% Homosalate 11.0% Octisalate 4.5% Octocrylene 8.0%	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 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-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, polybutene-2, neopentyl glycol diheptanoate, glycerin, aluminum starch octylsuccinate, styrene/acrylates copolymer, silica, phenyltrimethylammonium chloride, triethyl alcohol, hexamers, ethylhexylglycerin, acrylates/C10-30 alkyl acrylate copolymer, behenyl alcohol, tocopherol (vitamin E), arachidyl glucoside, glyceryl stearate, PEG-100 stearate, potassium hydroxide, disodium EDTA, sodium saccharin phosphate

Questions or comments?
Call toll free 1-800-827-7731

* No parabens separately added to preserve this product.
† Formula is compliant with Hawaii SB2571.

www.fote.com
At Fruit of the Earth® we pride ourselves in being 100% American owned and operated.
Follow/tag us in your photos:
@fote_usa
Instagram Facebook Twitter
Fruit of the Earth, Inc.
3325 W. Trinity Blvd.
Grand Prairie, TX 75050

FRUIT OF THE EARTH SUN TOWN CITY BABY SPF 50 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-074
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
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	

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)
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)
DOCOSANOL (UNII: 9G1OE216XY)
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)
WHITE WAX (UNII: 7G1J5DA97F)
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)
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:62217-074-82	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/10/2019	

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

Revised: 7/2021

Fruit of the Earth, Inc.