# 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.

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#### 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 \( \precip \) **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

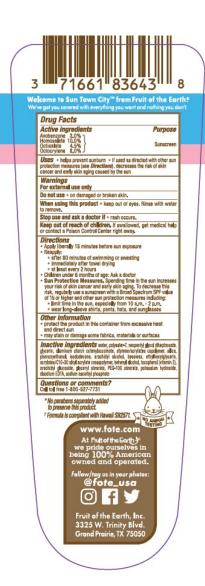
#### **| | | Other information**

- 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





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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	<b>Basis of Strength</b>	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	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: 19PJ0O6294)	
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: 9G10E216XY)	
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
WHITE WAX (UNII: 7G1J5DA97F)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
POTASSIUM HYDROXIDE (UNII: WZ H3C48M4T)	
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.