FRUIT OF THE EARTH SUN TOWN CITY SPF 30 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 SPF 30 Lotion Sunscreen

Active ingredients

Avobenzone 3.0%, Homosalate 8.0%, Octisalate 4.5%, Octocrylene 6.0%

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 casued by the sun

Warnings

For external use only

□Do not use

on damaged or broken skin.

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





Drug Facts
Active ingredients
Avobenzone 3.0%
Homosalate 8.0%
Octisalate 4.5%
Octocrylene 6.0%

Purpose

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

Cancer and early skin aging caused by the sun

Warmings
For external use only
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When using this product - issee you or dayse, Rinse with water
to remove.

Stop use and ask a doctor H - rash occurs.
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or contact a Poison Control Center right away.

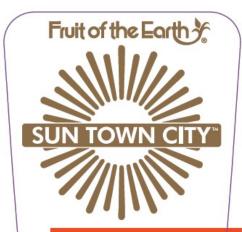
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Directions
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SPF 30 LOTION SUNSCREEN

BROAD SPECTRUM

- HYPOALLERGENIC ■
 PARABEN & PHTHALATE FREE* ■
 WATER RESISTANT (80 MINUTES) ■
- NO REEF-HARMING OXYBENZONE & OCTINOXATE

8.0 FL OZ (237 mL)

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

Paraben & Phthalate Free* No Reef-Harming Oxybenzone & Octinoxate*

Drug Facts	
Active ingredients	Purpose
Avobenzone 3,0% >	
Homosalate 8.0%	Sunscreen
Octisalate 4.5%	Sunscreen

Uses + helps prevent sunburn + if used as directed with other sun protection measures (see *Birections*), 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.

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 Directions

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 at least every 2 hours

 Children under 6 months of age: Ask a doctor

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At Fat of the Earth, Inc.

3325 W. Trinity 8 Ivd.

Grend Prairie, TX 75050

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* No parabens separately added to preserve this product.

† Formula is compliant with Hawaii SB2571.







FRUIT OF THE EARTH SUN TOWN CITY SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-079
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	80 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	60 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H)		
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		

CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)
DOCOSANOL (UNII: 9G10E216XY)
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01)
WHITE WAX (UNII: 7G1J5DA97F)
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)
PEG-100 STEARATE (UNII: YD01N1999R)
EDETATE DISODIUM (UNII: 7FLD91C86K)
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)
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)

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-079- 82	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2019	
2	NDC:62217-079- 83	44 mL in 1 TUBE; Type 0: Not a Combination Product	12/09/2019	
3	NDC:62217-079- 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.