

**FRUIT OF THE EARTH SUN TOWN CITY SPF 50 ZINC SUNSCREEN- octocrylene, zinc oxide 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 SPF 50 Zinc Sunscreen**

***Active ingredients***

Zinc Oxide 5.0%, Octocrylene 4.0%

***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, ethylhexyl stearate, diisopropyl adipate, cetyl dimethicone, cetyl PEG/PPG-10/1 dimethicone, hydrogenated castor oil, polyglyceryl-4 isostearate, hexyl laurate, beeswax, isohexadecane, phenoxyethanol, silica, ethylhexylglycerin, triethoxycaprylylsilane, dimethicone, sodium chloride, disodium EDTA, aloe barbadensis leaf powder, sodium ascorbyl phosphate, tocopherol, fragrance.

Fruit of the Earth<sup>®</sup>



**SUN TOWN CITY™**

**BROAD SPECTRUM  
SPF 50 ZINC  
SUNSCREEN**

**SPF 50**

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


1 FL OZ (29.6 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!**


At the beach, in the pool, and on the field, trust that Fruit of the Earth has got you covered! This **SPF 50 Zinc Sunscreen** with zinc oxide delivers vital moisturizing protection from skin-damaging and photo-aging UVA/UVB rays. Vitamins E and C help combat free radicals. Guard your skin with maximum protection that's kinder to the environment.

Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Zinc Oxide 5.0%	Sunscreen
Octocrylene 4.0%	
<b>Uses</b> • helps prevent sunburn • if used as directed with other sun protection measures (see <b>Directions</b> ), decreases the risk of skin cancer and early skin aging caused by the sun	
<b>Warnings</b> <b>For external use only</b> 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.	
<b>Directions</b> • 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	
<b>Other information</b> • protect the product in this container from excessive heat and direct sun • may stain or damage some fabrics, materials or surfaces	
<b>Inactive ingredients</b> water, ethylhexyl stearate, diisopropyl adipate, capryl dimethicone, capryl PEG/PPG-10/12 dimethicone, hydrogenated castor oil, polyacrylate-4 isochlorate, hexyl laurate, beeswax, isohexadecane, phenylethyl silox, ethylhexyl glycerin, methoxypropylamine, dimethicone, sodium citrate, disodium EDTA, ribe tartarates, zinc powder, sodium ascorbyl phosphate, tocopherol, fragrance.	
<b>Questions or comments?</b> Call toll free 1-800-527-7731	

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At Fruit of the Earth, we pride ourselves in being 100% American owned and operated.  
Fruit of the Earth, Inc.  
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Grand Prairie, TX 75050

 Follow us on your phone: @fote\_usa

\*No parabens especially added to preserve this product  
†Formula is compliant with Federal 2020/1



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**BROAD SPECTRUM  
SPF 50 ZINC  
SUNSCREEN**

**SPF 50**

1 FL OZ (29.6 mL)

**Active ingredients:** Zinc Oxide 5.0%, Octocrylene 4.0%. **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.



**FRUIT OF THE EARTH SUN TOWN CITY SPF 50 ZINC SUNSCREEN**  
octocrylene, zinc oxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62217-075
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	40 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	50 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>DIISOPROPYL ADIPATE</b> (UNII: P7E6YFV72X)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>CETYL DIMETHICONE 25</b> (UNII: U4AS1BW4ZB)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5)</b> (UNII: 035JKJ76MT)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>ETHYLHEXYL STEARATE</b> (UNII: EG3PA2K3K5)	
<b>HYDROGENATED CASTOR OIL</b> (UNII: ZF94AP8MEY)	
<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>.ALPHA.-TOCOPHEROL, DL-</b> (UNII: 7QWA1RIO01)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-075-43	1 in 1 CARTON	01/20/2020	
1	NDC:62217-075-42	29.6 mL in 1 JAR; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/20/2020	

