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.

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 \square **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.

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

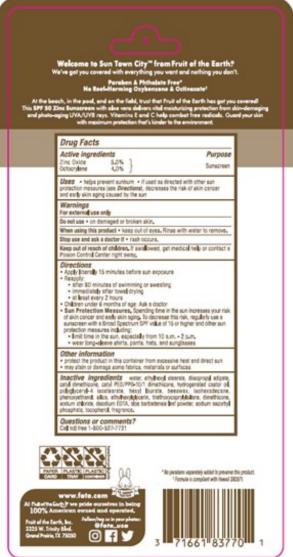
| | | Other information

- 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.







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octocrylene, zinc oxide lotion

Product Information

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

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

Inactive Ingredients	
Ingredient Name	Strength
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
WHITE WAX (UNII: 7G1J5DA97F)	
DIMETHICONE (UNII: 92RU3N3Y10)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	

ı	Packaging					
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
:	NDC:62217-075-	1 in 1 CARTON	01/20/2020			
:	NDC:62217-075-	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		

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

Revised: 7/2021 Fruit of the Earth, Inc.