# FRUIT OF THE EARTH SUN TOWN CITY BABY AND KIDS MINERAL SPF 50 SUNSCREEN- titanium dioxide, zinc oxide spray 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 and Kids Mineral SPF 50 Sunscreen Spray

#### **Active ingredients**

Titanium Dioxide 3.5%

Zinc Oxide 7.25%

#### **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

#### FLAMMABLE:

- do not use near heat, flame or while smoking
- avoid long term storage above 104°F (40°C)

#### Do not use

on damaged or broken skin

#### When using this product

- keep out of eyes. Rinse with water to remove.
- keep away from to avoid breathing it.
- do not puncture or incinerate. Contents under pressure.

• do not store at temperatures above 120° F.

#### Stop use and ask doctor if

rash occurs.

#### Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- hold can 4-6 inches away from skin top apply
- do not spray into face. Spray into hand and apply to face.
- use in a well ventilated areas

#### reapply:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- children under 6 months: 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 the container from excessive heat and direct sun
- may stain or damage some fabrics

### Inactive ingredients

Water, Isohexadecane, Isododecane, Caprylic/Capric Triglyceride, C12-15 Alkyl Benzoate, Neopentyl Glycol Diheptanoate, Shea Butter Ethyl Esters, Carthamus Tinctorius (Safflower) Seed Oil, C30-38 Olefin/Isopropyl Maleate/MA Copolymer, Butyloctyl Salicylate, Coco-Glucoside, Cetearyl Alcohol, Cetearyl Glucoside, Cetearyl Olivate, Sorbitan Olivate, Ethylhexylglycerin, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, Chlorphenesin, Xanthan Gum, Aloe Barbadensis Leaf Juice, Tocopherol, Glycerin, Sodium Gluconate, Citric Acid.

#### Label

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#### **Drug Facts**

Active ingredients Titanium Dioxide 3.5% Zinc Oxide 7.25%

Purpose Sunscreen

**Uses** • helps prevent sunburn • if used as directed with other sun protection measures (see *Directions*), the risk of skin cancer and early skin aging caused by the sun

Warnings For external use only

#### Flammable:

do not use near heat, flame or while smoking
avoid long term storage above 104°F (40°C)

Do not use on damaged or broken skin.

When using this product • keep out of eyes. Rinse with water to remove • keep away from face to avoid breathing it. • do not puncture or incinerate. Contents under pressure. • do not store at temperatures above 120° F.

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 • Spray liberally and spread evenly by hand 15 minutes before sun exposure • Hold can 4–6 inches away from the skin to apply • Do not spray directly into face. Spray into hands then apply to face • Do not apply in windy conditions • Use in a well-ventilated area. • 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 some fabrics

Inactive ingredients water, isohexadecane, isododecane, capryllic/capric triglyceride, C12-15 alkyl benzoate, neopentyl glycol diheptanoate, shea butter ethyl esters, carthamus finctorius (safflower) seed oil, C30-38 olefin/sopropyl maleate/MA copolymer, butyloctyl salicylate, coco-glucoside, cetearyl alchod, cetearyl glucoside, cetearyl ofivate, sorbitan olivate, ethylhexylglycerin, simmondsia chinensis (jojoba) seed oil, cocium butyonide chiporhisecerin varitten que a dea barbardensis sodium hydroxide, chlorphenesin, xanthan gum, aloe barbadensis leaf juice, tocopherol, glycerin, sodium gluconate, citric acid.

Questions or comments? Call 1-800-527-7731



#### www.fote.com

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Fruit of the Earth, Inc. 3325 W. Trinity Blvd. Grand Prairie, TX 75050

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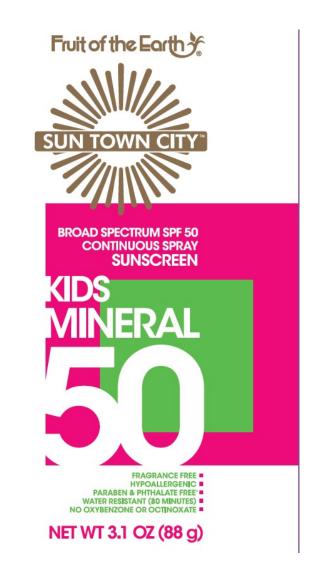
**BROAD SPECTRUM SPF 50 CONTINUOUS SPRAY SUNSCREEN** 



- FRAGRANCE FREE
- HYPOALLERGENIC ■
- PARABEN & PHTHALATE FREE: WATER RESISTANT (80 MINUTES)
- NO OXYBENZONE OR OCTINOXATE

NET WT 3.1 OZ (88 g)





### FRUIT OF THE EARTH SUN TOWN CITY BABY AND KIDS MINERAL SPF 50 SUNSCREEN

titanium dioxide, zinc oxide spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-242
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	35 mg in 1 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	72.5 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
CHLORPHENESIN (UNII: 1670DAL4SZ)		
WATER (UNII: 059QF0KO0R)		
ISOHEXADECANE (UNII: 918X1OUF1E)		

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ISODODECANE (UNII: A8289P68Y2)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
COCO GLUCOSIDE (UNII: ICS790225B)	
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
JOJOBA OIL (UNII: 724GKU717M)	
SHEA BUTTER ETHYL ESTERS (UNII: V2CI786FPG)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:62217-242- 08	88 g in 1 CAN; Type 0: Not a Combination Product	02/07/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	02/07/2022	

### Labeler - Fruit Of The Earth, Inc. (079559467)

Revised: 2/2023 Fruit Of The Earth, Inc.