## FRUIT OF THE EARTH SUN TOWN CITY DARK TANNING DRY OIL SPF 8 SUNSCREEN- homosalate, octisalate 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 Dark Tanning Dry Oil SPF 8 Continuous Spray Sunscreen

#### **Active Ingredients**

Homosalate 7.0%, Octisalate 5.0%

#### **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 casued 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.

#### $\square$ Stop use and ask a doctor if $\square$

rash occurs.

#### ☐Keep out of reach of children.

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

#### **Directions**

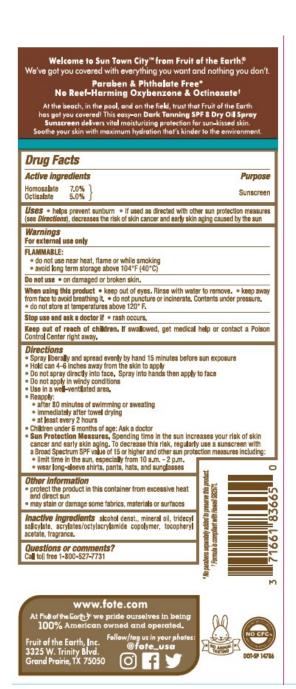
- Spray liberally and spread evenly by hand 15 minutes before sun exposure
- Hold can 4-6 inches away from the skin to apply
- Do not spray directly into face. Spray into hands then apply to face
- Do not apply in windy conditions
- Use in a well-ventilated area.
- Reapply:
- after 80 minutes of swimming 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, expecially from 10 a.m.-2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses

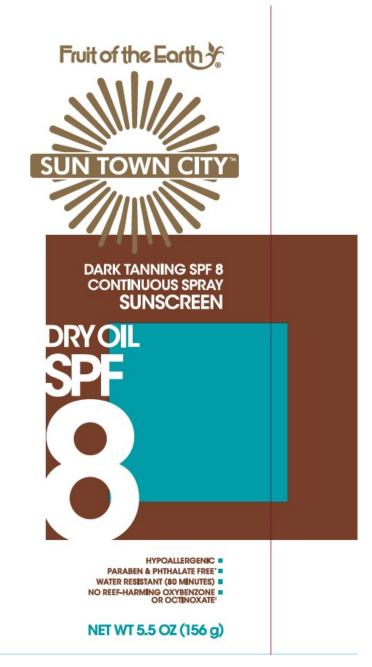
#### Other information

- protect the product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

#### Inactive ingredients

alcohol denat., mineral oil, tridecyl salicylate, acrylates/octylacrylamide copolymer, tocopheryl acetate, fragrance.





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homosalate, octisalate spray

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:62217-071 Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	70 mg in 1 g		
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g		

Inactive Ingredients			
Ingredient Name	Strength		
ALCOHOL (UNII: 3K9958V90M)			
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)			
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)			
MINERAL OIL (UNII: T5L8T28FGP)			
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			

ı	Packaging				
	# I	Item Code	Package Description	Marketing Start Date	Marketing End Date
	<b>1</b> NE 37		156 g in 1 CAN; Type 0: Not a Combination Product	11/27/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/27/2019	

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

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