

FRUIT OF THE EARTH SPORT SPF 50 SUNSCREEN CONTINUOUS- avobenzone, homosalate, octisalate, octocrylene, oxybenzone aerosol, 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.

Fruit of the Earth, Inc. Sport SPF 50 Sunscreen Continuous Spray

Active ingredients

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 4.0%, Oxybenzone 5.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn • higher SPF gives more sunburn protection

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 in. • 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 right away.

Directions

- apply liberally 15 minutes before sun exposure
- hold can 4-6 inches away from body, spray evenly to ensure complete coverage
- do not spray into face. Spray into hand and apply to face.
- use in well ventilated, but not windy areas
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- **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 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
- children under 6 months: ask a doctor

Other information

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

Inactive ingredients

alcohol denat. (73.2% v/v), acrylates/octylacrylamide copolymer, stearoxytrimethylsilane, glycerin, diethylhexyl syringylidenemalonate, tocopherol (vitamin E), ascorbic acid (vitamin C), aloe barbadensis leaf juice, fragrance (parfum), caprylic/capric triglyceride

Questions or comment?

Call toll free 1-800-527-7731

Fruit of the Earth, Inc. Sport SPF 50 Sunscreen Continuous Spray

FRUIT OF THE EARTH[®]

SPORT 50

CONTINUOUS SPRAY SUNSCREEN

BROAD SPECTRUM SPF 50

PARABEN FREE • DERMATOLOGIST TESTED
WATER RESISTANT (80 MINUTES)



5 FL OZ (148 ML)

Fruit of the Earth[®] SPORT 50 Continuous Spray Sunscreen delivers vital skin protection – broad spectrum UVA/UVB protection teamed up with moisturizing aloe vera and protective antioxidant vitamins C & E. This hypoallergenic sun defense formula sprays on quickly and easily for even coverage, even in hard to reach places, providing effective protection.

Drug Facts	
Active Ingredients	Purpose
Avobenzone 3.0% Homosalate 10.0% Octisalate 5.0% Octocrylene 4.0% Oxybenzone 5.0%	Sunscreen
Uses	
<ul style="list-style-type: none"> helps prevent sunburn higher SPF gives more sunburn protection 	
Warnings	
For external use only	
FLAMMABLE:	
<ul style="list-style-type: none"> 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 in. • 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 product is swallowed, get medical help right away.	
Directions	
<ul style="list-style-type: none"> apply liberally 15 minutes before sun exposure hold can 4-6 inches away from body, spray evenly to ensure complete coverage do not spray into face. Spray into hand and apply to face. use in well ventilated, but not windy areas reapply: <ul style="list-style-type: none"> after 80 minutes of swimming or sweating immediately after towel drying at least every 2 hours 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 of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> limit time in the sun, especially from 10 a.m. - 2 p.m. wear long-sleeve shirts, pants, hats, and sunglasses children under 6 months: ask a doctor 	
Other information	
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Inactive ingredients	
alcohol denat. (73.2% w/v), acrylates/octylacrylamide copolymer, stearyltrimethylsilane, glycerin, diethylhexyl syringidene malonate, tocopherol (vitamin E), ascorbic acid (vitamin C), aloe barbadensis leaf juice, fragrance (parfum), caprylic/capric triglyceride	
Questions or comments?	
Call toll free 1-800-527-7731	



Contains Oxybenzone
Fruit of the Earth, Inc.
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www.fote.com

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avobenzone, homosalate, octisalate, octocrylene, oxybenzone aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL

AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	40 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEAROXYTRIMETHYLSILANE (UNII: 9862TW94B2)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
ALCOHOL (UNII: 3K9958V90M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-012-35	148 mL in 1 CAN; Type 0: Not a Combination Product	05/16/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/16/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(62217-012)

Revised: 5/2017

Fruit of the Earth, Inc.