

FRUIT OF THE EARTH BLOCK UP LITE BROAD SPECTRUM SPF 15 CONTINUOUS SUNSCREEN- avobenzone, homosalate, octisalate, 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. Block Up! Lite Broad Spectrum SPF 15 Continuous Sunscreen Spray

Active ingredients

Avobenzone 2.0%, Homosalate 10.0%, Octisalate 5.0%, Oxybenzone 3.0%

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**

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. • 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

- 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. (82.23% v/v), acrylates/octylacrylamide copolymer, glycerin, aloe barbadensis leaf juice, tocopherol (vitamin E), fragrance, ascorbic acid (vitamin C)

Questions or comment?

Call toll free 1-800-527-7731

Fruit of the Earth, Inc. Block Up! Lite Broad Spectrum SPF 15 Continuous Sunscreen Spray

Clear
No-Rub Spray

Fruit of the Earth®

BLOCK UP!®

SPF **15**
SUNSCREEN

CONTINUOUS SPRAY

Broad Spectrum SPF 15

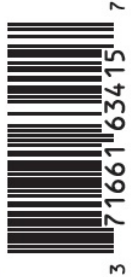
With soothing ALOE VERA
Water resistant (80 minutes)
UVA/UVB Protection

6 FL OZ (177mL)

Non-Stop!
Spray & Go with Block Up!®

Block Up! Continuous Spray SPF 15 delivers a light water-resistant blend of Aloe-Vera, Vitamins C & E and Sunscreen in a QUICK, EASY SPRAY. Quick drying formula for on-the-go UVA/UVB protection: Anywhere, Anytime. PABA-Free, No Pumping Required.

Drug Facts	
Active ingredients	Purpose
Avobenzone 2.0% Homosalate 10.0% Octisalate 5.0% Oxybenzone 3.0%	Sunscreen
Uses • helps prevent sunburn • If used as directed with other sun protection measures (see <i>Directions</i>), 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. • 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 or contact a Poison Control Center 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	
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Questions or comments? Call toll free 1-800-527-7731	



Fruit of the Earth, Inc.
3101 High River Road, Ste. 175, Fort Worth, TX 76155
MADE IN USA with U.S. and foreign parts
www.fote.com

Block Up! is a Registered Trademark of Fruit of the Earth, Inc.



DOT-SP 14786
MS655

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avobenzone, homosalate, octisalate, oxybenzone aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-028
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	20 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL

OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30 mg in 1 mL
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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)	
ALCOHOL (UNII: 3K9958V90M)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-028-25	177 mL in 1 CAN; Type 0: Not a Combination Product	06/09/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/09/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(62217-028)

Revised: 6/2017

Fruit of the Earth, Inc.