

**FRUIT OF THE EARTH BLOCK UP SPF 30 GENERAL PROTECTION SUNSCREEN-
avobenzene, octinoxate, octisalate, octocrylene, oxybenzone 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 Block Up! SPF 30 General Protection Sunscreen Lotion

Active ingredients

Avobenzene 2.0%, Octinoxate 7.5%, Octisalate 5.0%, Octocrylene 1.5%, Oxybenzone 5.0%

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

Do not use

- on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

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

• 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

Inactive ingredients

water (aqua), C12-15 alkyl benzoate, PEG-8, acrylates/C12-22 alkyl methacrylate copolymer, cetearyl alcohol, dicetyl phosphate, ceteth-10 phosphate, aloe barbadensis leaf juice, tocopheryl acetate (vitamin E), sodium ascorbyl phosphate (vitamin C), arnica montana flower extract, chamomilla recutita (matricaria) flower extract, geranium maculatum extract, cucumis sativus (cucumber) fruit extract, euphrasia officinalis extract, tilia cordata flower extract, althaea officinalis root extract, yucca schidigera extract, hydrated silica, potassium cetyl phosphate, propylene glycol, phenoxyethanol, methylparaben, propylparaben, butylparaben, ethylparaben, isobutylparaben, acrylates/C10-30 alkyl acrylate crosspolymer, triethanolamine, disodium EDTA, fragrance (parfum)


Other information

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

Questions or comments?

Call toll free 1-800-527-7731

Fruit of the Earth Block Up! SPF 30 General Protection Sunscreen Lotion



BLOCK UP![®]

30

general protection
sunscreen

BROAD SPECTRUM SPF 30

with **ALOE VERA**
anti-oxidant vitamins C and E
water resistant (80 minutes)

8 FL OZ (237mL)

Block Up! Broad Spectrum SPF 30 Sunscreen
with avobenzone gives skin the best protection available from UVA1, 2 & UVB rays. Proven protection from all skin-damaging rays. SPF 30 protects against BURNS, PREMATURE AGING & SKIN CANCER, year-round!

• Broad Spectrum UVA & UVB Protection • Moisturizing, Water-Resistant Formula

Drug Facts	
Active ingredients	Purpose
Avobenzone 2.0% Octinoxate 7.5% Octisalate 5.0% Octocrylene 1.5% Oxybenzone 5.0%	Sunscreen
Uses	
<ul style="list-style-type: none"> • 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 	
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Fort Worth, TX 76155
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237mL e  NO ANIMAL TESTING
www.fote.com

FRUIT OF THE EARTH BLOCK UP SPF 30 GENERAL PROTECTION SUNSCREEN

avobenzone, octinoxate, octisalate, octocrylene, oxybenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-019
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	15 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
TILIA CORDATA FLOWER (UNII: CFN6G1F6YK)	
YUCCA SCHIDIGERA (UNII: 08A0YG3VIC)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A218C7H9T)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GERANIUM MACULATUM ROOT (UNII: 93IXI5B6OJ)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
CUCUMBER (UNII: YY7C30VXJT)	
EUPHRASIA STRICTA (UNII: C9642I91WL)	
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-019-11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part352	05/25/2017	
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Labeler - Fruit of the Earth, Inc. (079559467)

Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(62217-019)

Revised: 5/2017

Fruit of the Earth, Inc.