

FRUIT OF THE EARTH BLOCK UP SPORT SPF 30 SUNSCREEN- avobenzone, 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! Sport SPF 30 Sunscreen Lotion

Active ingredients

Avobenzone 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

Other information

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

Inactive ingredients

water (aqua), C12-15 alkyl benzoate, PEG-8, cetearyl alcohol, acrylates/C12-22 alkyl methacrylate copolymer, dicetyl phosphate, ceteth-10 phosphate, aloe barbadensis leaf juice, tocopheryl acetate (vitamin E acetate), sodium ascorbyl phosphate (vitamin C phosphate), chamomilla recutita (matricaria) flower extract, citrus limon (lemon) peel extract, geranium maculatum extract, calendula officinalis flower extract, salvia officinalis (sage) leaf extract, arctium lappa root extract, melissa officinalis leaf extract, propylene glycol, potassium cetyl phosphate, phenoxyethanol, methylparaben, propylparaben, butylparaben, ethylparaben, isobutylparaben, hydrated silica, acrylates/C10-30 alkyl acrylate crosspolymer, triethanolamine, disodium EDTA, fragrance (parfum)

Questions or comments?

Call toll free 1-800-527-7731

Fruit of the Earth Block Up! Sport SPF 30 Sunscreen Lotion



BLOCK UP![®]

30

sport
sunscreen

BROAD SPECTRUM SPF 30

with **ALOE VERA**
antioxidant vitamins C and E
water resistant (80 minutes)

1 FL OZ (30 mL)



Drug Facts	
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Avobenzene 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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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 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.	
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Questions or comments?	
Call toll free 1-800-527-7731	

30mL e



NO ANIMAL TESTING

www.fote.com

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Made in U.S.A. with U.S.
and foreign parts

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FRUIT OF THE EARTH BLOCK UP SPORT SPF 30 SUNSCREEN

avobenzene, octinoxate, octisalate, octocrylene, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-009
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)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3)	
LEMON (UNII: 24RS0A988O)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
SAGE (UNII: 065C5D077J)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
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)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-009-16	30 mL in 1 TUBE; Type 0: Not a Combination Product	05/16/2017	
2	NDC:62217-009-11	237 mL in 1 BOTTLE; 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(62217-009)

Revised: 8/2017

Fruit of the Earth, Inc.