

FRUIT OF THE EARTH BLOCK UP SPORT SPF 50 SUNSCREEN- avobenzone, homosalate, 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, Inc. Block Up! Sport SPF 50 Sunscreen Lotion

Active ingredients

Avobenzone 2.0%, Homosalate 9.0%, Octinoxate 7.5%, Octisalate 5.0%, Octocrylene 1.5%, Oxybenzone 5.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection

Warnings

For external use only

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

Stop use and ask doctor if rash or irritation develops and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply generously and evenly before sun exposure and as needed.
- reapply as needed or after towel drying, swimming, or perspiring.
- children under 6 months of age: ask a doctor

Other information

- may stain some fabrics
- Sun alert: Limiting sun exposure, wearing protective clothing, and

using sunscreen may reduce the risks of aging, skin cancer, and other harmful effects of the sun.

Inactive ingredients

water (aqua), C12-15 alkyl benzoate, PEG-8, acrylates/C12-22 alkyl methacrylate copolymer, cetearyl alcohol (and) dicetyl phosphate (and) ceteth-10 phosphate, aloe barbadensis leaf juice, tocopheryl acetate (vitamin E), retinyl palmitate (vitamin A), sodium ascorbyl phosphate (vitamin C), anthemis nobilis flower extract (and) citrus medica limonum (lemon) peel extract (and) geranium maculatum extract (and) calendula officinalis flower extract (and) salvia officinalis (sage) leaf extract (and) arctium

lappa root extract (and) melissa officinalis root extract (and) juglans nigra (black walnut), propylene glycol, potassium cetyl phosphate, phenoxyethanol (and) methylparaben (and) propylparaben (and) butylparaben (and) ethylparaben (and) isobutylparaben, hydrated silica, acrylates C/10-30 alkyl acrylate crosspolymer, disodium EDTA, fragrance (parfum)

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**THE CUTTING EDGE OF SUNCARE ...
BLOCK UP!® FULL SPECTRUM!**

New Full Spectrum Sport 50 with Avobenzone gives skin the best protection available from UVA 1, 2 & UVB rays. Complete protection with Sport 50's quick-drying active formula. Won't Slow You Down!

Drug Facts	
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American owned and operated!

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FRUIT OF THE EARTH BLOCK UP SPORT SPF 50 SUNSCREEN

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-024
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
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	90 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)	
LEMON PEEL (UNII: 72O054U628)	
ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3)	
BLACK WALNUT (UNII: 02WM57RXZJ)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QPII03FV8)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
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)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
SAGE (UNII: 065C5D077J)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-024-09	88 mL in 1 TUBE; Type 0: Not a Combination Product	06/02/2017	
2	NDC:62217-024-11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/02/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(62217-024)

Revised: 8/2017

Fruit of the Earth, Inc.