

FRUIT OF THE EARTH BLOCK UP 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, Inc. Block Up! 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
- 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), arnica montana flower extract (and) chamomilla recutita (matricaria) flower extract (and) geranium maculatum extract (and) cucumis sativus (cucumber) fruit extract (and)

euphrasia officinalis extract (and) tilia cordata flower extract (and) althaea officinalis root extract (and) yucca schidigera extract, hydrated silica, potassium cetyl phosphate, propylene glycol, phenoxyethanol (and) methylparaben (and) propylparaben (and) butylparaben (and) ethylparaben (and) isobutylparaben, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, fragrance (parfum)

Fruit of the Earth, Inc. Block Up! SPF 30 Sunscreen Lotion

Fruit of the Earth

BLOCK UP!

Full Spectrum
UVA/UVB Protection

SPF 30
with **ALOE VERA**

Avobenzone
Protects Against Premature Aging

Anti-Oxidant Vitamins A, C & E
Water/Sweat Resistant

3 FL.OZ. (88ml)

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

New Full Spectrum SPF 30 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!

Drug Facts	
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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 ■ higher SPF gives more sunburn protection 	
Warnings	
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When using this product ■ keep out of eyes. Rinse with water to remove.	
Stop use and ask a 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	
<ul style="list-style-type: none"> ■ 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	
<ul style="list-style-type: none"> ■ 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. 	
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USA American owned and operated!

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FRUIT OF THE EARTH BLOCK UP SPF 30 SUNSCREEN

avobenzone, octinoxate, octisalate, octocrylene, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-021
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	50 mg in 1 mL
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

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: 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)	
CUCUMBER (UNII: YY7C30VXJT)	
EUPHRASIA STRICTA (UNII: C9642I91WL)	
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-021-09	88 mL in 1 TUBE; 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(62217-021)

Revised: 6/2017

Fruit of the Earth, Inc.