

FRUIT OF THE EARTH, INC. ULTRA SPF 50 MOISTURIZING SUNSCREEN- avobenzene, 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. Ultra SPF 50 Moisturizing Sunscreen Lotion

Active ingredients

Avobenzene 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**

☐ **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 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, aloe barbadensis leaf juice, 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 leaf/root/stem extract, dicetyl phosphate, tocopherol acetate, sodium ascorbyl phosphate, hydrated silica, potassium cetyl phosphate propylene glycol, phenoxyethanol, potassium sorbate, caprylyl glycol, hexylene glycol, 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, Inc. Ultra SPF 50 Moisturizing Sunscreen Lotion



FRUIT OF THE EARTH®

ULTRA 50

MOISTURIZING LOTION SUNSCREEN

BROAD SPECTRUM SPF 50

WITH ALOE VERA • WATER RESISTANT (80 MINUTES)
PARABEN FREE • DERMATOLOGIST TESTED

3 FL OZ (88 ML)

Fruit of the Earth® ULTRA 50 Lotion Sunscreen

delivers vital skin protection – broad spectrum UVA/UVB protection teamed up with moisturizing aloe vera, and protective antioxidant vitamins C & E. This hypoallergenic sun defense formula dries quickly and easily for even coverage providing effective protection.

Drug Facts

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Contains Oxybenzone

Fruit of the Earth, Inc.
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Fort Worth, TX 76155
www.fote.com



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	90 mg in 1 mL

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

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CHAMOMILE (UNII: FGL3685T2X)	
GERANIUM MACULATUM ROOT (UNII: 93IXI5B6OJ)	
CUCUMBER (UNII: YY7C30VXJT)	
EUPHRASIA STRICTA (UNII: C9642I91WL)	
TILIA CORDATA FLOWER (UNII: CFN6G1F6YK)	
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	
YUCCA SCHIDIGERA (UNII: 08A0YG3VIC)	
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-006-03	88 mL in 1 TUBE; Type 0: Not a Combination Product	05/12/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/12/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(62217-006)

Revised: 8/2017

Fruit of the Earth, Inc.