

FRUIT OF THE EARTH SPORT SPF 50- 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 Sport SPF 50 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 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 value 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-sleeved shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Other information

- protect the product in this container 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, anthemis nobilis 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, juglans nigra (black walnut) leaf extract, dicetyl phosphate, ceteth-10 phosphate, tocopheryl acetate, sodium ascorbyl phosphate, propylene glycol, potassium cetyl phosphate, phenoxyethanol, potassium sorbate, caprylyl glycol, hexylene glycol, hydrated silica, acrylates/C10-30 alkyl acrylate crosspolymer, triethanolamine, disodium EDTA, fragrance (parfum)

FRUIT OF THE EARTH

SPORT
50

MOISTURIZING LOTION
SUNSCREEN

BROAD SPECTRUM SPF 50

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

1 FL OZ (30 ML)



Drug Facts

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Questions or comments?

Call toll free 1-800-527-7731



www.fote.com Contains Oxybenzone
Fruit of the Earth, Inc. 3101 High River Rd. Ste. 175 Fort Worth, TX 76155

FRUIT OF THE EARTH[®]

SPORT 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[®] SPORT 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.

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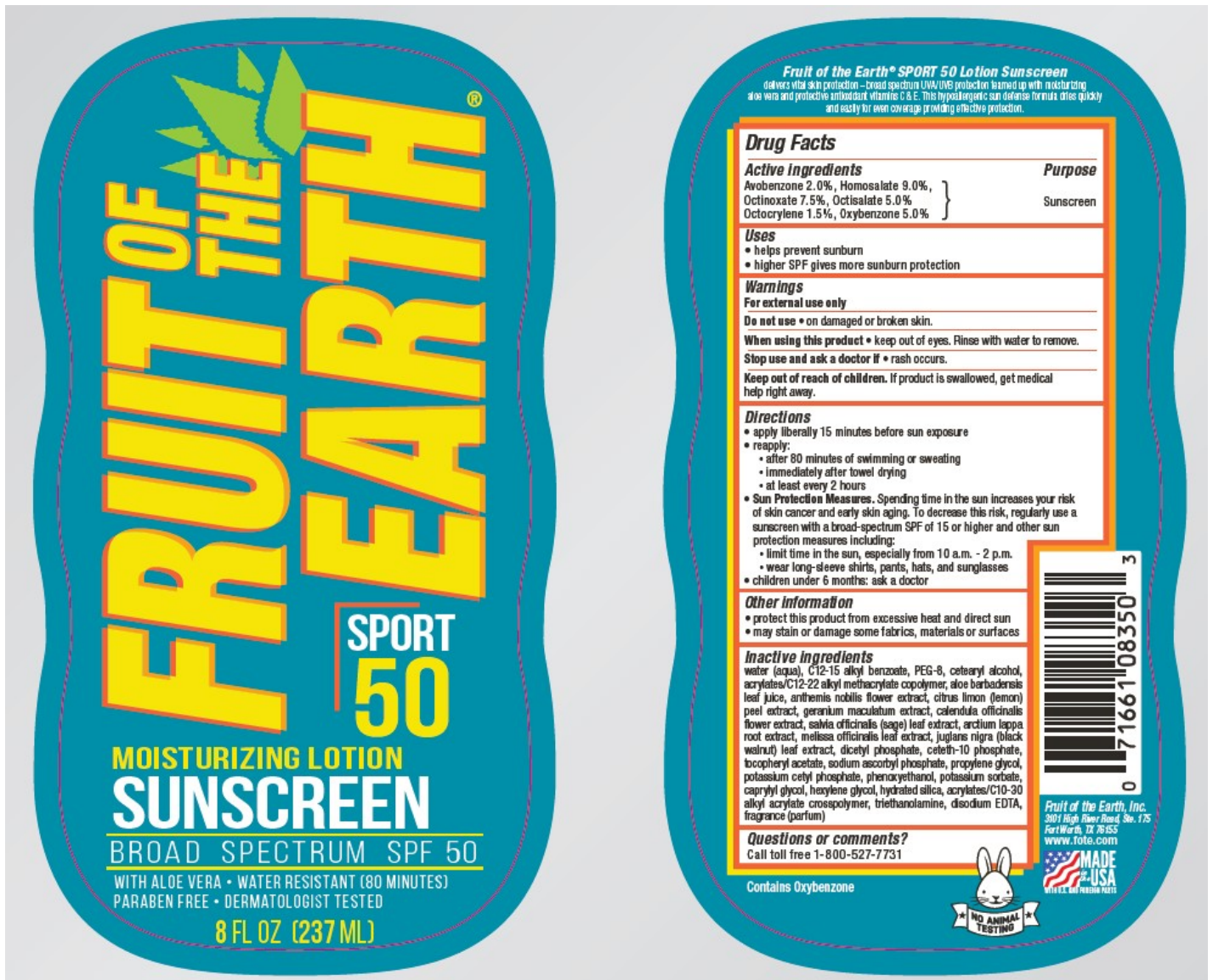
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-350
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GERANIUM MACULATUM ROOT (UNII: 93IXI5B6OJ)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
JUGLANS NIGRA LEAF (UNII: I2OQ2W1NI2)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836S5G51DR)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
LEMON PEEL (UNII: 72O054U628)	
SAGE (UNII: 065C5D077J)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5VN99N)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-350-16	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/20/2016	
2	NDC:62217-350-09	88 mL in 1 TUBE; Type 0: Not a Combination Product	07/20/2016	
3	NDC:62217-350-11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/20/2016	

