

FOTE SPORT SUNSCREEN SPF 50- avobenzone, homosalate, octisalate, octocrylene 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.

SPA COLOGY SPORT SUNSCREEN LOTION SPF 50

Active ingredients

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 4.5%, Octocrylene 8.0%

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 a doctor if

- rash occurs

Keep out of reach of children.

If 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
 - children under 6 months of age: Ask a doctor
- **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

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, polyester-7, neopentyl glycol diheptanoate, glycerin, styrene/acrylates copolymer, aluminum starch octenylsuccinate, silica, phenoxyethanol, isododecane, arachidyl alcohol, beeswax, ethylhexylglycerin, acrylates/C10-30 alkyl acrylate crosspolymer, behenyl alcohol, tocopherol (vitamin E), arachidyl glucoside, glyceryl stearate, PEG-100 stearate, potassium hydroxide, disodium EDTA, sodium ascorbyl phosphate, fragrance

Label

SPA COLOGY SPORT SUNSCREEN LOTION SPF 50

8.0 FL OZ (237mL)

NDC 62217-052-11



FOTE SPORT SUNSCREEN SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYESTER-7 (UNII: 0841698D2F)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKWBC543X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ISODODECANE (UNII: A8289P68Y2)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
WHITE WAX (UNII: 7G1J5DA97F)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H)	
DOCOSANOL (UNII: 9G1OE216XY)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35J0OJ)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-052-11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/15/2017	

Labeler - FRUIT OF THE EARTH, INC. (079559467)