

**FRUIT OF THE EARTH BLOCK UP BROAD SPECTRUM BABY 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.*

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**Fruit of the Earth Block Up! Broad Spectrum Baby SPF 50**

**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
- 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 doctor**

if rash occurs.

**Keep out of reach of children.**

If product is 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
- **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

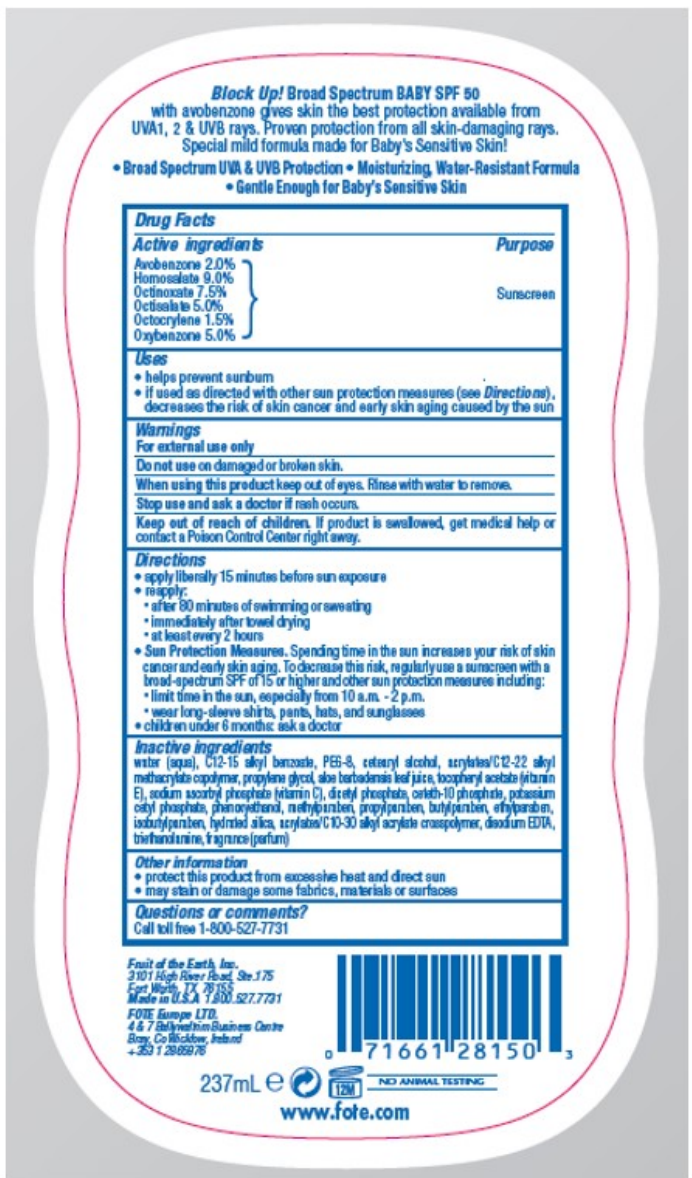
## Inactive ingredients

water (aqua), C12-15 alkyl benzoate, PEG-8, cetearyl alcohol, acrylates/C12-22 alkyl methacrylate copolymer, propylene glycol, aloe barbadensis leaf juice, tocopheryl acetate (vitamin E), sodium ascorbyl phosphate (vitamin C), dicetyl phosphate, ceteth-10 phosphate, potassium cetyl phosphate, phenoxyethanol, methylparaben, propylparaben, butylparaben, ethylparaben, isobutylparaben, hydrated silica, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, triethanolamine, fragrance (parfum)

## Other information

- protect the product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

## Label



## FRUIT OF THE EARTH BLOCK UP BROAD SPECTRUM BABY SPF 50

avobenzone, homosalate, octinoxate, octisalate, octocrylene, oxybenzone lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62217-174
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	90 mg in 1 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	15 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER</b> (UNII: 7K68DGG29P)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)	
<b>DIHEXADECYL PHOSPHATE</b> (UNII: 2V6E5WN99N)	
<b>CETETH-10 PHOSPHATE</b> (UNII: 4E05O5N49G)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
<b>ISOBUTYLPARABEN</b> (UNII: 0QQJ25X58G)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 809Y72KV36)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-174-05	237 mL in 1 TUBE; Type 0: Not a Combination Product	08/24/2011	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/24/2011	

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