

FRUIT OF THE EARTH BLOCK UP SPORT SPF 50 NO MESS SUN- avobenzene, homosalate, octisalate, octocrylene, oxybenzone stick

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 Block Up! Sport SPF 50 No Mess Sunstick

Active ingredients

Avobenzene 3.0%, Homosalate 15.0%, Octisalate 5.0%, Octocrylene 10.0%, Oxybenzone 3.0%

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 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

paraffin, C12-15 alkyl benzoate, octyldodecyl neopentanoate, adipic acid/diglycol crosspolymer, ozokerite, beeswax, dimethicone, neopentyl glycol diethylhexanoate, neopentyl glycol diisostearate, caprylyl glycol, BHT, fragrance

Questions or comments?

Call toll free 1-800-527-7731

Fruit of the Earth Block Up! Sport SPF 50 No Mess Sunstick

BLOCK UP!

Fruit of the Earth

SPORT 50

NO MESS SUNSTICK

BROAD SPECTRUM SPF 50

NET WT 1.5 OZ (42 G)

Fruit of the Earth BLOCK UP!® SPORT SPF 50 Sunstick provides water and sweat resistant UVA/UVB sun protection specifically formulated for fun at the beach! This hands-free, no mess stick contains a lightweight formula that absorbs fast and glides on easily.

PEEL HERE

BLOCK UP! – Essential Gear for Fun In the Sun!



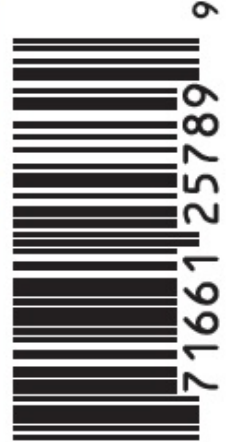
Fruit of the Earth, Inc.
3101 High River Road, Ste. 175
Fort Worth, TX • 76155
www.fote.com



Block Up! is a Registered Trademark of Fruit of the Earth, Inc.

Drug Facts

Active ingredients	Purpose
Avobenzone 3%	☉ Sunscreen
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Octisalate 5%	
Octocrylene 10%	
Oxybenzone 3%	



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Drug Facts (continued)

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	30 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	150 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PARAFFIN (UNII: I9O0E3H2ZE)	
ADIPIC ACID/DIGLYCOL CROSSPOLYMER (20000 MPAS) (UNII: R9TPS68K19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)	
NEOPENTYL GLYCOL DIISOSTEARATE (UNII: 4M6OQ34JWW)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-018-36	42 g in 1 PACKAGE; Type 0: Not a Combination Product	05/25/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/25/2017	

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

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(62217-018)

Revised: 8/2017

Fruit of the Earth, Inc.