

**FRUIT OF THE EARTH BLOCK UP KIDS 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 Block Up! Kids 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 • 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 • **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, propylene glycol, dicetyl phosphate, ceteth-10 phosphate, aloe barbadensis leaf juice, tocopheryl acetate (vitamin E), sodium ascorbyl phosphate (vitamin C), calendula officinalis flower extract, symphytum officinale rhizome/root extract, arctium lappa root extract, hydrastis canadensis (golden seal) root extract, honey extract, anthemis nobilis flower extract, tilia cordata flower extract, hydrated silica, potassium cetyl phosphate, phenoxyethanol, methylparaben, propylparaben, butylparaben, ethylparaben, isobutylparaben, acrylates/C10-30 alkyl acrylate crosspolymer, triethanolamine, disodium EDTA

Questions or Comments?

Call toll free 1-800-527-7731

Fruit of the Earth Block Up! Kids SPF 50 Moisturizing Sunscreen Lotion

Fruit of the Earth BLOCK UP!® KIDS Moisturizing 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, skin renewing and defensive formula dries quickly and easily for even coverage, providing effective protection for up to 80 minutes of sun exposure.
BLOCK UP! – Essential Gear for Fun in the Sun!

Fruit of the Earth®

Drug Facts

Active ingredients	Purpose
Avobenzone 2.0%	Sunscreen
Homosalate 9.0%	
Octinoxate 7.5%	
Octisalate 5.0%	
Octocrylene 1.5%	
Oxybenzone 5.0%	

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 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

water (aqua), C12-15 alkyl benzoate, PEG-8, cetearyl alcohol, acrylates/C12-22 alkyl methacrylate copolymer, propylene glycol, dicetyl phosphate, ceteth-10 phosphate, aloe barbadensis leaf juice, tocopheryl acetate (vitamin E), sodium ascorbyl phosphate (vitamin C), calendula officinalis flower extract, symphytum officinale rhizome/root extract, arctium lappa root extract, hydrastis canadensis (golden seal) root extract, honey extract, anthemis nobilis flower extract, tilia cordata flower extract, hydrated silica, potassium cetyl phosphate, phenoxyethanol, methylparaben, propylparaben, butylparaben, ethylparaben, isobutylparaben, acrylates/C10-30 alkyl acrylate crosspolymer, triethanolamine, disodium EDTA

Questions or comments?

Call toll free 1-800-527-7731



BLOCK UP!
KIDS 50



MOISTURIZING LOTION
SUNSCREEN

BROAD SPECTRUM SPF 50

WATER RESISTANT (80 MINUTES)
DERMATOLOGIST TESTED


WITH ALOE VERA

6 FL OZ (177 ML)

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.

The SKIN CANCER FOUNDATION recommends this product as an effective broad spectrum sunscreen.



BLOCK UP!®

50

kids
sunscreen

BROAD SPECTRUM SPF 50

with **ALOE VERA**
antioxidant vitamins C and E
water resistant (80 minutes)

8 FL OZ (237mL)

Block Up! Broad Spectrum KIDS SPF 50
with avobenzone gives skin the best protection available from UVA1, 2 & UVB rays. Proven protection from all skin-damaging rays. Special mild formula made for Kids' Sensitive Skin!

- Broad Spectrum UVA & UVB Protection • Moisturizing, Water-Resistant Formula
- Gentle Enough for Kids' Sensitive Skin

Drug Facts	
Active ingredients	Purpose
Avobenzone 2.0% Homosalate 9.0% Octinoxate 7.5% Octisalate 5.0% Octocrylene 1.5% Oxybenzone 5.0%	Sunscreen
Uses	
<ul style="list-style-type: none"> • 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 product is swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • apply liberally 15 minutes before sun exposure • reapply: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 	
Inactive ingredients	
water (aqua), C12-15 alkyl benzoate, PEG-8, cetearyl alcohol, acrylates/C12-22 alkyl methacrylate copolymer, propylene glycol, diethyl phosphate, ceteth-10 phosphate, aloe barbadensis leaf juice, tocopheryl acetate (vitamin E), sodium ascorbyl phosphate (vitamin C), calendula officinalis flower extract, symphytum officinale rhizome/root extract, arctium lappa root extract, hydrastis canadensis (golden seal) root extract, honey extract, anthemis nobilis flower extract, tilia cordata flower extract, hydrated silica, potassium cetyl phosphate, phenoxyethanol, methylparaben, propylparaben, butylparaben, ethylparaben, isobutylparaben, acrylates/C10-30 alkyl acrylate crosspolymer, triethanolamine, disodium EDTA	
Other information	
<ul style="list-style-type: none"> • protect this product from excessive heat and direct sun • may stain or damage some fabrics, materials or surfaces 	
Questions or comments?	
Call toll free 1-800-527-7731	

Fruit of the Earth, Inc.
3101 High River Road, Ste.175
Fort Worth, TX 76155
Made in U.S.A 1.800.527.7731
FOTE Europe LTD.
4 & 7 Ballyvaughan Business Centre
Bray, Co Wicklow, Ireland
+353 1 2865976



237mL e   NO ANIMAL TESTING
www.fote.com

FRUIT OF THE EARTH BLOCK UP KIDS SPF 50 MOISTURIZING SUNSCREEN

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

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-013
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	90 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
TROLAMINE (UNII: 9O3K93S3TK)	
ETHYLPARABEN (UNII: 14255EXE39)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
BUTYLPARABEN (UNII: 3QP1I1U3FV8)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
HONEY (UNII: Y9H1V576FH)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
TILIA CORDATA WHOLE (UNII: W5E5UB44GD)	
COMFREY ROOT (UNII: M9VVZ08EKQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-013-15	177 mL in 1 TUBE; Type 0: Not a Combination Product	05/23/2017	
2	NDC:62217-013-11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/23/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	--	----------------------	--------------------

OTC monograph not final	part352	05/23/2017	
-------------------------	---------	------------	--

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

Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(62217-013)

Revised: 5/2017

Fruit of the Earth, Inc.