FRUIT OF THE EARTH BLOCK UP KIDS SPF 50 MOISTURIZING SUNSCREENavobenzone, 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

Avobenzone 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

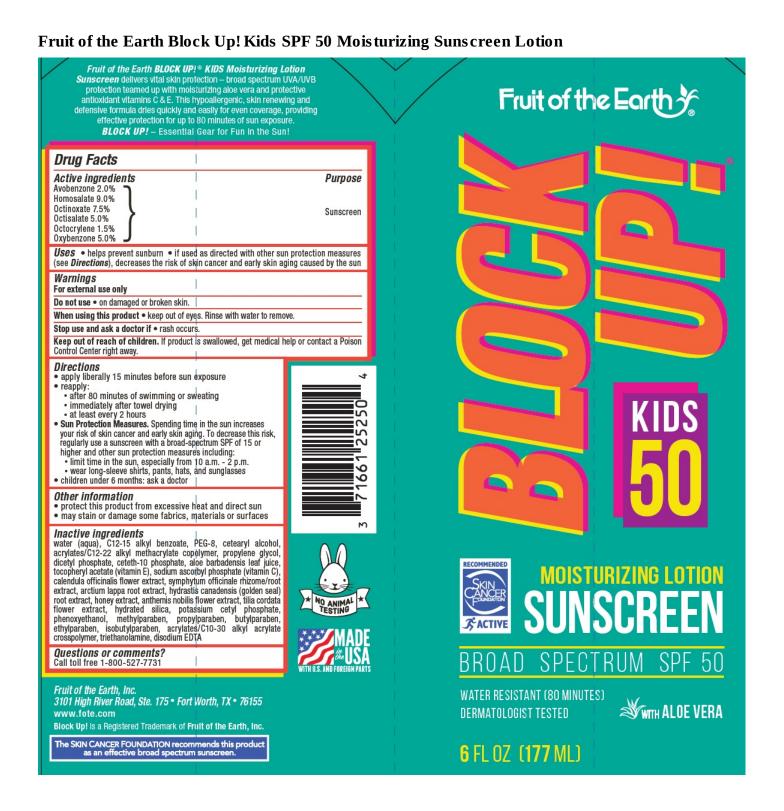
Inactive ingredients

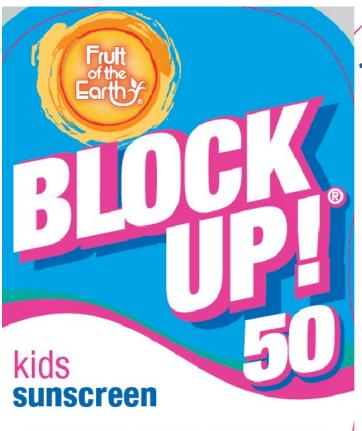
water (aqua), C12-15 alkyl benzoate, PEG-8, cetearyl alcohol, acrylates/C12-22 alkyl methacrylate

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





BROAD SPECTR



8 FL 0Z (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

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

Sunscreen

- 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

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When using this product keep out of eyes. Rinse with water to remove.

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- reapply:
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- immediately after towel drying
 at least every 2 hours
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 • 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, dicetyl phosphate, ceteth-10 phosphate, aloe barbadensis leaf juice,
tocopheryl acetate (vitamin E), sodium ascorbyl phosphate (vitamin C), calendula officinals flower extract,
symphylum officinale rhizome/root extract, arctium lappa root extract, hydrastis canadensis (golden seal)
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potassium cetyl phosphate, phenoxyethanol, methylparaben, propylparaben, butylparaben, ethylparaben,
isobutylparaben, acrylates/C10-30 alkyl acrylate crosspolymer, triethanolamine, disodium EDTA

Other information

- 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 Ballywaltrim Business Centre Bray, Co Wicklow, Ireland +353 1 2865976



237mL 🖯 🥙

FRUIT OF THE EARTH BLOCK UP KIDS SPF 50 MOISTURIZING SUNSCREEN

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

Product Information

HUMAN OTC DRUG Product Type NDC:62217-013 Item Code (Source)

Route of Administration TOPICAL

Active Ingradient/Active Majety

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Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL	

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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: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	50 mg in 1 mL
OXYBENZONE (UNII: 950OS7VE0Y) (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 Stre	ngth
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
ALOE VERA LEAF (UNII: ZY81Z83H0 X)	
POTASSIUM CETYL PHO SPHATE (UNII: 03KCY6P7UT)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CETETH-10 PHO SPHATE (UNII: 4E05O5N49G)	
DIHEXADECYL PHO SPHATE (UNII: 2V6 E5WN99N)	
ISOBUTYLPARABEN (UNII: 0 QQJ25X58G)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
TROLAMINE (UNII: 903K93S3TK)	
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)	
.ALPHATO COPHEROL ACETATE, D- (UNII: A7E6112E4N)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836 SJG51DR)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
HONEY (UNII: Y9H1V576FH)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
TILIA CORDATA WHOLE (UNII: W5E5UB44GD)	
COMFREY ROOT (UNII: M9 VVZ08 EKQ)	

]	Packaging				
1	# 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

3 3 7	* *	· .	9	
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.