

EQUATE SUNSCREEN KIDS SPF50 BROAD SPECTRUM- avobenzone, homosalate, octisalate, octocrylene spray
WAL-MART STORES 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.

Equate Sunscreen KIDS SPF50 Broad Spectrum Spray

Active ingredients

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 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 aging caused by the sun

Warnings

For external use only.

FLAMMABLE:

- do not use near heat, flame or while smoking
- avoid long term storage above 104°F (40°C)

Do not use • on damaged or broken skin.

When using this product • keep out of eyes. Rinse with water to remove. • Keep away from face to avoid breathing it. • do not puncture or incinerate. Contents under pressure. • do not store at temperatures above 120° F.

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

- Spray liberally and spread evenly by hand 15 minutes before sun exposure
- Hold can 4-6 inches away from the skin to apply
- Do not spray directly into face. Spray into hands then apply to face
- Do not apply in windy conditions
- Use in a well-ventilated area
- 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 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

Other information

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

Inactive ingredients

alcohol denat., isododecane, diisopropyl adipate, acrylates/octylacrylamide copolymer, VA/butyl maleate/isobornyl acrylate copolymer, PEG-12 dimethicone, caprylyl glycol, hydrogenated methyl abietate, ascorbyl palmitate, tocopheryl acetate, mineral oil, panthenol, water, aloe barbadensis leaf extract, fragrance

Equate Sunscreen Kids SPF 50 Broad Spectrum Spray

equate™

SPF 50 KIDS Sunscreen
Broad Spectrum SPF 50 Spray

Sunscreen

SPF 50

KIDS

Broad Spectrum SPF 50

- Water resistant (80 minutes)
- Pediatrician tested

OXYBENZONE & PARABEN FREE

Drug Facts	
Active ingredients	Purpose
Avobenzone 3.0% Homosalate 10.0% Octisalate 5.0% Octocrylene 5.0%	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	
FLAMMABLE: • do not use near heat, flame or while smoking • avoid long term storage above 104°F (40°C)	
Do not use • on damaged or broken skin.	
When using this product • keep out of eyes. Rinse with water to remove. • Keep away from face to avoid breathing it. • do not puncture or incinerate. Contents under pressure. • do not store at temperatures above 120° F.	
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 • Spray liberally and spread evenly by hand 15 minutes before sun exposure • Hold can 4-6 inches away from the skin to apply • Do not spray directly into face. Spray into hands then apply to face • Do not apply in windy conditions • Use in a well-ventilated area • 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 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	
Other information • protect this product from excessive heat and direct sun • may stain or damage some fabrics, materials or surfaces	
Inactive ingredients alcohol denat., isododecane, diisopropyl acipate, acrylates/octylacrylamide copolymer, VA/butyl maleate/isobornyl acrylate copolymer, PEG-12 dimethicone, caprylyl glycol, hydrogenated methyl abietate, ascorbyl palmitate, tocopheryl acetate, mineral oil, panthenol, water, aloe barbadensis leaf extract, fragrance	



Blended and Filled in the U.S.A. with Imported and Domestic Ingredients

Satisfaction guaranteed - For questions or comments please call 1-888-287-1915.

DISTRIBUTED BY: Wal-Mart Stores, Inc., Bentonville, AR 72716



*No parabens separately added to preserve this product DOT-SP 14786



EQUATE SUNSCREEN KIDS SPF50 BROAD SPECTRUM

avobenzone, homosalate, octisalate, octocrylene spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-845
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
	OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	50 mg in 1 g
	HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
	OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MINERAL OIL (UNII: T5L8T28FGP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
PANTHENOL (UNII: WV9CM0067Z)	
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)	
VINYL ACETATE (UNII: L9MK238N77)	
ISODODECANE (UNII: A8289P68Y2)	
HYDROGENATED METHYL ABIETATE (UNII: A23O709X8O)	
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-845-37	156 g in 1 CAN; Type 0: Not a Combination Product	01/21/2019	
2	NDC:49035-845-39	312 g in 1 CAN; Type 0: Not a Combination Product	01/21/2019	
3	NDC:49035-845-48	258 g in 1 CAN; Type 0: Not a Combination Product	01/21/2019	
4	NDC:49035-845-78	516 g in 1 CAN; Type 0: Not a Combination Product	12/03/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/21/2019	

Labeler - WAL-MART STORES INC (051957769)

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

Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(49035-845)

Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth, Inc.		080086802	manufacture(49035-845)

