FRUIT OF THE EARTH LUV THAT SUN KIDS SUNSCREEN ULTRA SPF 50-avobenzone, homosalate, octisalate, octocrylene lotion FRUIT OF THE EARTH, INC.

Fruit of the Earth LUV THAT SUN Kids Sunscreen Ultra Lotion SPF 50

Active ingredients

Avobenzone 3.0%, Homosalate 15.0%, 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 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
- 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 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

Other information

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

Inactive ingredients

water, tridecyl salicylate, propylene glycol, styrene/acrylates copolymer, polyamide-8, neopentyl glycol diheptanoate, oleth-3, acrylates/C10-30 alkyl acrylate crosspolymer, triethanolamine, tocopherol, disodium EDTA, chlorphenesin, benzyl alcohol, fragrance

Label



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avobenzone, homosalate, octisalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-405
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	150 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	30 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
OLETH-3 (UNII: BQZ26235UC)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TRIDECYL SALICYLATE (UNII: AZ Q08K38Z1)	
TROLAMINE (UNII: 903K93S3TK)	
POLYAMIDE-8 (4500 MW) (UNII: 77723GV81A)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H)	

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:62217-405- 25	177 mL in 1 TUBE; Type 0: Not a Combination Product	09/06/2022	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	09/06/2022		

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

Revised: 10/2024 FRUIT OF THE EARTH, INC.