FRUIT OF THE EARTH VITAMIN E SPF 15 SUNSCREEN DAILY DEFENSE MOISTURIZER- avobenzone, octinoxate, 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 Vitamin E SPF 15 Sunscreen Daily Defense Moisturizer

Active ingredients

Octinoxate 7.5%, Octisalate 5.0%, Oxybenzone 3.0%

Purpose

Sunscreen

Uses

• helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

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 at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- children under 6 months of age: Ask a doctor

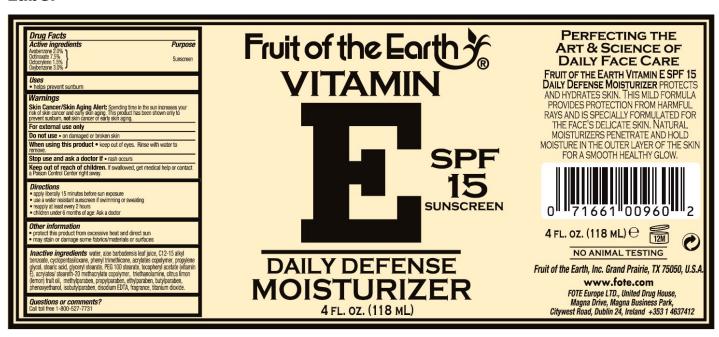
Other information

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

Inactive ingredients

water, aloe barbadensis leaf juice, c12-15 alkyl benzoate, cyclopentasiloxane, phenyl trimethicone, acrylates copolymer, propylene glycol, stearic acid, glyceryl stearate, PEG 100 stearate, tocopheryl acetate (vitamin E), acrylates/steareth-20 methacrylate copolymer, triethanolamine, citrus limon (lemon) fruit oil, methylparaben, propylparaben, ethylparaben, butylparaben, phenoxyethanol, isobutylparaben, disodium EDTA, fragrance, titanium dioxide.

Label



FRUIT OF THE EARTH VITAMIN E SPF 15 SUNSCREEN DAILY DEFENSE MOISTURIZER

avobenzone, octinoxate, octocrylene, oxybenzone lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-252	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	15 mg in 1 mL		
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	30 mg in 1 mL		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ETHYL ACRYLATE/METHACRYLIC ACID/STEARETH-20 METHACRYLATE COPOLYMER (UNII: EPA1872R1N)	
LEMON OIL (UNII: 19GRO824LL)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
TROLAMINE (UNII: 903K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ETHYLPARABEN (UNII: 14255EXE39)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2005		

Marketing In	arketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M020	06/13/2005		

Revised: 2/2023 FRUIT OF THE EARTH, INC.