FRUIT OF THE EARTH LUV THAT SUN SPORT SUNSCREEN CONTINUOUS SPF 50-avobenzone, homosalate, octisalate, octocrylene spray 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 LUV THAT SUN Sport Sunscreen Continuous Spray SPF 50

Active ingredients

Avobenzone 3.0%

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 4.0%

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

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 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

alcohol denat., butyloctyl salicylate, acrylates/octylacrylamide copolymer, panthenol, tocopherol, fragrance,

Labels



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avobenzone, homosalate, octisalate, octocrylene spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-401	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	30 mg in 1 g		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	100 mg in 1 g		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	40 mg in 1 g		
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g		

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01)		
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)		
ALCOHOL (UNII: 3K9958V90M)		
PANTHENOL (UNII: WV9CM0O67Z)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
STEAROXYTRIMETHYLSILANE (UNII: 9862TW94B2)		
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:62217-401-	156 g in 1 CAN; 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 final	M020	09/06/2022		

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

Revised: 6/2023 FRUIT OF THE EARTH, INC.