

FRUIT OF THE EARTH SPF 50 KIDS SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, oxybenzone aerosol, 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.

Spa Cology Kids Sunscreen Broad Spectrum SPF 50 Continuous Spray

Active Ingredients

Avobenzone 3.0%,

Homosalate 10.0%,

Octisalate 5.0%,

Octocrylene 4.0%,

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

FLAMMABLE

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

Do not use

on damaged or broken skin

When using this product

- keep out of eyes. Rinse with water to remove.

- Do not puncture or incinerate. Contents under pressure.
- Do not store at temperatures above 120 deg F.

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
- Hold can 4-6 inches away from body, spray evenly to ensure complete coverage
- Do not spray into face. Spray into hand and apply to face.
- Use in well ventilated, but not windy areas

- Reapply:
 - After 80 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours

- 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 am - 2 pm
 - wear long sleeved shirts, pants, hats, and sunglasses

- children under 6 months: Ask a doctor

Inactive Ingredients

Alcohol denat. (73.2% v/v), acrylates/octylacrylamide copolymer, stearytrimethylsilane, glycerin, diethylhexyl syringylidene malonate, tocopherol (vitamin E), fragrance, retinyl palmitate (vitamin A palmitate), caprylic/capric triglyceride

Other information

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



KIDS SUNSCREEN

SPF 50

CONTINUOUS SPRAY

BROAD SPECTRUM SPF 50

WATER RESISTANT (80 MINUTES)
PARABEN FREE*
HYPOALLERGENIC

NET WT 5.5 OZ (156 G)



KIDS SUNSCREEN SPF 50 CONTINUOUS SPRAY
PROVIDES EFFECTIVE BROAD SPECTRUM UVA/UVB PROTECTION THAT SPRAYS ON EASILY AND ABSORBS QUICKLY. THIS OIL-FREE, HYPOALLERGENIC FORMULA IS SPECIALLY FORMULATED FOR FOR KIDS' SENSITIVE SKIN. SPAGOLGY PROVIDES THE BEST SUNGARE POSSIBLE WITH GENTLE, NATURAL, NOURISHING ELEMENTS.

Drug Facts	
Active ingredients	Purpose
Avobenzone 3.0% Homosalate 10.0% Octisalate 5.0% Octocrylene 4.0% Oxybenzone 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., acrylates/octylacrylamide copolymer, stearoxytrimethylsilane, glycerin, diethylhexyl syringylidenemalonate, tocopherol (vitamin E), fragrance, retinyl palmitate (vitamin A palmitate), caprylic/capric triglyceride	



*NO PARABENS SEPARATELY ADDED TO PRESERVE THIS PRODUCT



DOT-SP 14786

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avobenzone, homosalate, octisalate, octocrylene, oxybenzone aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-208
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	40 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
STEAROXYTRIMETHYLSILANE (UNII: 9862TW94B2)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
TOCOPHEROL (UNII: R0ZB2556P8)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-208-37	156 g in 1 CAN; Type 0: Not a Combination Product	11/14/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/04/2014	

Labeler - Fruit Of The Earth, Inc. (079559467)

Revised: 1/2022

Fruit Of The Earth, Inc.