KIDS SUNSCREEN SPF 50- avobenzone 3.0% homosalate 15.0% octisalate 5.0% octocrylene 10.0% spray

Wegman

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.

Active ingredients

Purpose

Avobenzone 3%	Sunscreen
Homosalate 15%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 10%	Sunscreen

Uses • helps prevent sunburn • higher SPF gives more sunburn protection • retains SPF after 80 minutes of activity in the water or sweating • provides high protection against sunburn

Warnings

For external use only

Flammable: Do not use near heat, flme, or while smoking.

Do not use on damaged or broken skin

When using this product • Keep out of eyes. Rinse eyes 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 • spray liberally and spread evenly by hand 15 minutes before sun exposure • reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • hold container 4 to 6 inches from the skin to apply • do not spray directly into face. Spray on hands then apply to face. • do not apply in windy conditions • use in a well-ventilated area

- **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
- children under 6 months: Ask a doctor

Inactive ingredients: Acrylates/Octylacrylamide, Copolymer, Alcohol Denat., Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Fragrance, Glycerin, Stearoxytrimethylsilane, Tocopherol.

Questions?

1-800-Wegmans (934-6267) Ext 5920 9am - 4pm EST weekdays



Drug Facts

Active ingredients	Purpose
Avobenzone 3%	Sunscreer
Homosalate 15%	Sunscreer
Octisalate 5%	Sunscreer
Octocrylene 10%	Sunscreer

Uses • helps prevent sunburn • higher SPF gives more sunburn protection · retains SPF after 80 minutes of activity in the water or sweating · provides high protection against sunburn

Warnings

Flammable: Do not use near heat, flame, or while smoking.

For external use only

Do not use on damaged or broken skin.

When using this product keep away from face to avoid breathing it . keep out of eyes. Rinse eyes 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.

Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.

Directions • Spray liberally and spread evenly by hand 15 minutes before sun exposure . Reapply: . after 80 minutes of swimming or sweating · immediately after towel drying · at least every 2 hours · Hold container 4 to 6 inches from the skin to apply . Do not spray directly into face. Spray on hands then apply to face. . Do not apply in windy conditions . Use in a well-ventilated area . Children under 6 months: 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-sleeve shirts, pants, hats, and sunglasses

Other information • protect the product in this container from excessive heat and direct sun . may stain some fabrics.

Inactive ingredients Acrylates/Octylacrylamide Copolymer,

Alcohol Denat., Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Fragrance, Glycerin, Stearoxytrimethylsilane, Tocopherol.

Questions?

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Distributed By: Wegmans Food Markets, Inc. Rochester, NY 14603

We guarantee it!

The Wegmons Family



KIDS SUNSCREEN SPF 50

avobenzone 3.0% homosalate 15.0% octisalate 5.0% octocrylene 10.0% spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:47124-116

Route of Administration TOPICAL

Active Ingredient/Active Majety

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Ingredient Name	Basis of Strength	Strength	
Avobenzone (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	Avobenzone	3.0 in 100 g	
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	Homosalate	15.0 in 100 g	
Octisalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	5.0 in 100 g	
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	10.0 in 100 g	
		U	

Inactive Ingredients			
Ingredient Name	Strength		
ALCOHOL (UNII: 3K9958V90M)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
Diethylhexyl Syringylidenemalonate (UNII: 3V5U97P248)			
Glycerin (UNII: PDC6A3C0OX)			
Stearoxytrimethylsilane (UNII: 9862TW94B2)			
Tocopherol (UNII: R0 ZB2556 P8)			

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:47124-116-10	340 g in 1 CAN; Type 0: Not a Combination Product	05/18/2018	
l	2 NDC:47124-116-05	170 g in 1 CAN; Type 0: Not a Combination Product	05/18/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/18/2018	

Labeler - Wegman (059650069)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg, LLC		927768135	manufacture(47124-116), label(47124-116)	

Revised: 7/2018 Wegman