SUNSCREEN SPF 50 WEGMAN- avobenzone 3.0% homosalate 15.0% octisalate 5.0% octocrylene 10.0% lotion 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.

Drug Facts

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

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 or irritation develops and lasts

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 and as needed. • Children under 6 months of age: ask a doctor.
• Reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours. • **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. • For sunscreen use: • apply to all skin exposed to the sun. • reapply as needed or after towel drying, swimming, or sweating

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

Inactive ingredients

Aluminum Starch Octenylsuccinate, Carbomer, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Phenoxyethanol, Polyglyceryl-3 Distearate, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol,

Questions? 1-800-Wegmans(934-6267) Ext 5920

9am - 4pm EST weekdays.



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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47124-113
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Avobenzone (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	Avobenzone	3 g in 100 mL	
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	15 g in 100 mL	
Octisalate (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	Octisalate	5 g in 100 mL	
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	10 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
Aluminum Starch Octenylsuccinate (UNII: 19 PJ0 O 6 29 4)			
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)			
Dimethicone (UNII: 92RU3N3Y1O)			
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)			
Ethylhexylglycerin (UNII: 147D247K3P)			
Phenoxyethanol (UNII: HIE492ZZ3T)			
Polyglyceryl-3 Distearate (UNII: ZI1LK470XV)			
Sorbitan Isostearate (UNII: 01S2G2C1E4)			
Sorbitol (UNII: 506T60A25R)			
Stearic Acid (UNII: 4ELV7Z65AP)			
Tocopherol (UNII: R0ZB2556P8)			
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)			
TROLAMINE (UNII: 903K93S3TK)			
Water (UNII: 059QF0KO0R)			

l	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:47124-113-05	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2013		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	03/01/2013		

Labeler - Wegman (059650069)

Registrant - Product Quest Mfg (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg		927768135	manufacture(47124-113), label(47124-113)	

Revised: 5/2018 Wegman