

**KIDS SUNSCREEN SPF 50- avobenzone 3.00% homosalate 15.00% octisalate 5.00% octocrylene 10.00% 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.*

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**Wegman**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
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 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 and as needed.
- 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. • 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 fabrics.

**Inactive ingredients**

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

Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water

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

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Wegmans Food Markets, Inc.  
Rochester, NY 14603  
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*The Wegmans Family*

**KIDS SUNSCREEN SPF 50**

avobenzone 3.00% homosalate 15.00% octisalate 5.00% octocrylene 10.00% lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:47124-112
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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<b>Avobenzone</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	Avobenzone	3 g in 100 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	5 g in 100 mL
<b>Octocrylene</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	10 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Homosalate</b> (UNII: V06SV4M95S)	15 g in 100 mL
<b>Aluminum Starch Octenylsuccinate</b> (UNII: I9PJ0O6294)	
<b>CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Polyglyceryl-3 Distearate</b> (UNII: ZIILK470XV)	
<b>Sorbitan Isostearate</b> (UNII: 01S2G2C1E4)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>EICOSYL POVIDONE</b> (UNII: XQQ9MKE2BJ)	
<b>Water</b> (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47124-112-05	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(47124-112) , label(47124-112)