# KIDS SUNSCREEN SPF 50 WEGMANS- homosalate - 6.00% octinoxate - 7.50% octisalate - 5.00% octocrylene - 10.00% zinc oxide - 8.00% stick 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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## **Drug Facts**

Active ingredients	Purpose
Homosalate 6.0%	Sunscreen
Octinoxate 7.5%	Sunscreen
Octisalate 5.0%	Sunscreen
Octocrylene 10.0%	Sunscreen
Zinc Oxide 8.0%	Sunscreen

**Uses** • helps prevent sunburn

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## 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
- 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 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**

1,2-Hexanediol, Aloe Barbadensis Leaf Extract, C12-15 Alkyl Benzoate, Caprylyl Glycol, Ceresin, Chamomilla Recutita (Matricaria) Flower Extract, Copernicia Cerifera (Carnauba) Wax, Dimethicone, Ethyl Macadamiate, Ethylhexyl Palmitate, Helianthus Annuus (Sunflower) Seed Oil, Hydrogenated

Polyisobutene, Hydrogenated Vegetable Oil, Lavandula Angustifolia (Lavender) Extract, Octyldodecanol, Polyethylene, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sorbitan Sesquioleate, Tocopheryl Acetate, Triethoxycaprylylsilane



# Drug Facts Active ingredients Purpose Homosalate 6.0%......Sunscreen Octinoxate 7.5%.....Sunscreen Octisalate 5.0%.....Sunscreen Octocrylene 10.0%.....Sunscreen Zinc Oxide 8.0%.....Sunscreen Uses • helps prevent 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 reapply: • after 40 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 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 1.2-Hexanediol, Aloe Barbadensis Leaf Extract, C12-15 Alkyl Benzoate, Caprylyl Glycol, Ceresin, Chamomilla Recutita (Matricaria) Flower Extract, Copernicia Cerifera (Carnauba) Wax, Dimethicone, Ethyl Macadamiate, Ethylhexyl Palmitate, Helianthus Annuus (Sunflower) Seed Oil, Hydrogenated Polyisobutene, Hydrogenated Vegetable Oil, Lavandula Angustifolia (Lavender) Extract, Octyldodecanol, Polyethylene, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sorbitan Sesquioleate, Tocopheryl Acetate, Triethoxycaprylylsilane. Other information • protect this product from excessive heat and direct sun. Questions or comments? 1-800-Wegmans(934-6267) Ext 5920 9am - 4pm EST weekdays. Distributed By: Wegmans Food Markets, Inc. Rochester, NY 14603

# We guarantee it!

The Wegmons Family



#### KIDS SUNSCREEN SPF 50 WEGMANS

homosalate - 6.00% octinoxate - 7.50% octisalate - 5.00% octocrylene - 10.00% zinc oxide - 8.00% stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47124-338
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	Homosalate	6 g in 100 g	
Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 100 g	
Octisalate (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	Octisalate	5 g in 100 g	
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	10 g in 100 g	
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	8 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
1,2-Hexanediol (UNII: TR046 Y3K1G)	
Aloe (UNII: V5VD430 YW9)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
Caprylyl Glycol (UNII: 00 YIU5438 U)	
Ceresin (UNII: Q1LS2UJO3A)	
CARNAUBA WAX (UNII: R12CBM0 EIZ)	
Dimethicone (UNII: 92RU3N3Y1O)	
Ethyl Macadamiate (UNII: ANA2NCS6V1)	
Ethylhexyl Palmitate (UNII: 2865993309)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWERING TOP (UNII: 9 YT4B71U8P)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
Mineral Oil (UNII: T5L8T28FGP)	
Octyldodecanol (UNII: 461N1O614Y)	
ALMOND OIL (UNII: 66 YXD4DKO9)	
Sorbitan Sesquioleate (UNII: 0 W8 RRI5W5A)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	

ı	Packaging			
ı	# Item Code Package Description		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 NDC:47124-338-01	14.2 g in 1 TUBE; Type 0: Not a Combination Product	0 1/0 3/20 13	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 1/0 3/20 13	

# **Labeler -** Wegman (059650069)

# Registrant - Product Quest Mfg (927768135)

Establishment			
Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(47124-338), label(47124-338)

Revised: 1/2018 Wegman