# WEGMANS SHEER BROAD SPECTRUM SPF 30 DRY TOUCH SUNSCREENavobenzone, homosalate, octisalate, octocrylene lotion WEGMANS FOOD MARKETS 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.

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# Wegmans Sheer Broad Spectrum SPF 30 Dry Touch Sunscreen Lotion

## **Active ingredients**

Avobenzone 3.0%, Homosalate 8.0%, Octisalate 5.0%, Octocrylene 4.0%

## **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 aging caused by the sun

# 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 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
- 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 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

#### Other information

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

# **Inactive ingredients**

water, tridecyl salicylate, silica, dimethicone, potassium cetyl phosphate, beeswax, benzyl alcohol, glyceryl stearate, PEG-100 stearate, cetyl dimethicone, caprylyl methicone, caprylyl glycol, ethyhexylglycerin, dimethicone/PEG-10/15 crosspolymer, sodium polyacrylate, behenyl alcohol, xanthan gum, ethylhexyl stearate, acrylates/C12-22 alkyl methacrylate copolymer, disodium EDTA, chlorphenesin, fragrance, trideceth-6, propylene glycol

#### Label



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avobenzone, homosalate, octisalate, octocrylene lotion

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	<b>Basis of Strength</b>	Strength			
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 mL			
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	40 mg in 1 mL			
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL			
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL			

Inactive Ingredients	
Ingredient Name	Strength
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DOCOSANOL (UNII: 9G10E216XY)	
DIMETHICONE (UNII: 92RU3N3Y10)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETYL DIMETHICONE 45 (UNII: IK315POC44)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
TRIDECYL SALICYLATE (UNII: AZ Q08K38Z1)	

l	P	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
		NDC:47124-124- 09	89 mL in 1 TUBE; Type 0: Not a Combination Product	02/25/2019			

Marketing In	formation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/25/2019	

# Labeler - WEGMANS FOOD MARKETS INC (059650069)

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