

**WESTERN FAMILY SPF 15- avobenzone, homosalate, octisalate, octocrylene lotion**  
**WESTERN FAMILY FOODS, 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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**Drug Facts**

**Active ingredients**

Avobenzone 2.0%

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 5.0%

**Purpose**

Sunscreen

**Uses**

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decrease the risk of skin cancer and early skin 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. May stain some fabrics.

**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 of age: Ask a doctor

### **Inactive ingredients**

Water, Ethylhexyl Palmitate, Sorbitol, Polyglyceryl-3 Methylglucose Distearate, Benzyl Alcohol, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Glyceryl Stearate, PEG-100 Stearate, Triethanolamine, Disodium EDTA, Carbomer, Tocopherol, Aloe Barbadensis Leaf Juice Powder, Chlorphenesin, Fragrance.

### **Other Information**

- protect this product from excessive heat and direct sun

### **Principal Display Panel**

WESTERN FAMILY

Broad Spectrum

SPF 15

sunscreen lotion

UVA/UVB protection

moisturizing with vitamin e

water resistant

(80 minutes)

10 FL OZ (295 mL)



Drug Facts														
<b>Active Ingredients</b>	<b>Purpose</b>													
Azobenzene 2.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 5.0%	Sunscreen													
<b>Uses</b> • helps prevent sunburn • If used as directed with other sun protection measures (see <b>Directions</b> ) decreases the risk of skin cancer and early skin aging caused by the sun														
<b>Warnings</b> 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 • Stay out of sun 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. • May stain some fabrics.														
<b>Directions</b> • apply liberally 15 minutes before sun exposure • reapply after 80 minutes of swimming or sweating • immediately after towel drying • reapply every 2 hours • See <b>Precautions</b> . 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. to 2 p.m. • wear long-sleeve shirts, pants, hats and sunglasses • children under 6 months of age: Ask a doctor														
<b>Inactive Ingredients</b> Water, Ethylhexyl Palmitate, Stearic Acid, Polyglyceryl-3 Methacrylate Dimethacrylate, Benzyl Alcohol, Acrylates C12-15, Allyl Methacrylate Copolymer, Dimethicone, Acrylates C12-15, Acrylate Copolymer, Glyceryl Stearate, PEG-100 Stearate, Tris(hydroxymethyl) Aminomethane, Carbomer, Tocopherol, Aloe Barbadensis Leaf Juice Powder, Cholesterol, Fragrance.														
<b>Other information</b> • protect this product from excessive heat and direct sun														
<b>Questions or comments?</b> Call 1-800-439-3484														
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Questions or comments?

Call 1-503-639-6300

## WESTERN FAMILY SPF 15

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:55312-017

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SORBITOL (UNII: 506T60A25R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CHLORPHENESIN (UNII: I670DAL4SZ)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-017-57	290 g in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/07/2014	

Labeler - WESTERN FAMILY FOODS, INC. (192166072)

### Establishment

Name	Address	ID/FEI	Business Operations
Playtex Manufacturing Inc		963501502	manufacture(55312-017)

Revised: 7/2014

WESTERN FAMILY FOODS, INC.