

WESTERN FAMILY OIL FREE FACES SPF 30- avobenzone homosalate octisalate octocrylene oxybenzone 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.

Drug Facts

Active ingredients

Avobenzone 2.0 %

Homosalate 13.0%

Octisalate 5.0%

Octocrylene 2.0%

Oxybenzone 4.0%

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.

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

Other information

- protect this product from excessive heat and direct sun

Inactive ingredients

Water, Sorbitol, Stearic Acid, Triethanolamine, Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Sorbitan Isostearate, VP/Eicosene Copolymer, Dimethicone, Polyglyceryl-3 Distearate, Carbomer, Tocopherol, Disodium EDTA, Methylparaben, Propylparaben, Fragrance.

Principal Display Panel

WESTERN FAMILY

oil free faces

broad spectrum SPF 30

sunscreen lotion

UVA/UVB protection

wont clog pores

Water Resistant (80 Minutes)

3 FL OZ (88 mL)

Drug Facts

Active Ingredients	Purpose
Avobenzone 2.0%, Homosalate 13.0%, Octisalate 1.0%, Octocrylene 1.0%, Oxybenzone 4.0%	Sunscreen

Uses - helps prevent tanning - If used as directed with other skin protection measures (see Above Box), decreases 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 product is 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 • See Precautions
Precautions - 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

Other Ingredients Water, Sorbitol, Stearic Acid, Triethanolamine, Aluminum Starch Octylsuccinate, Benzyl Alcohol, Sorbitan Isodecylate, VPi/Eicosene Copolymer, Dimethicone, Polyglyceryl-3 Diethersilicate, Carbomer, Tocopherol, Disodium EDTA, Methylparaben, Propylparaben

Other information - protect this product from excessive heat and direct sun

Questions or Comments?
 Call 1-333-639-6300

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 Western Family Foods, Inc.
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MADE IN USA

13286-A-100

560037845

WESTERN FAMILY

oil free faces

broad spectrum SPF 30
 sunscreen lotion

UVA/UVB protection

won't clog pores
 water resistant (30 minutes)

3 FL OZ (88 mL)

Questions or comments?

Call 1-503-639-6300

WESTERN FAMILY OIL FREE FACES SPF 30
 avobenzone homosalate octisalate octocrylene oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-015
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	13 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-015-22	85 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	07/02/2014	

Labeler - WESTERN FAMILY FOODS, INC. (192166072)