

**WESTERN FAMILY BABY BROAD SPECTRUM SUNSCREEN SPF 50-
avobenzone, homosalate, octocrylene, octisalate, 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 3.0%

Homosalate 13.0%

Octisalate 5.0%

Octocrylene 7.0%

Oxybenzone 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 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 the 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
- **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, 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.

Other information

- protect this product from excessive heat and direct sun

Questions or comments?

Call 1-503-639-6300

Principal Display Panel

WESTERN FAMILY

baby Broad Spectrum SPF 50

sunscreen lotion

UVA/UVB protection

pediatrician tested

water resistant

(80 minutes)

10 FL OZ (295 mL)



Drug Facts

Active ingredients	Purpose
Avobenzone 3.0%, Homosalate 13.0%, Octisalate 1.0%, Octocrylene 7.0%, Oxybenzone 4.0%	Sunscreen

Uses • helps prevent sunburn • If used as directed with other sun protection measures (see Directions), 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 the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away. • **May irritate babies.**

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, regular use of 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 4 p.m. • wear long-sleeved shirts, pants, hats and sunglasses • children under 6 months of age. Ask a doctor.

Inactive ingredients: Water, Glycerin, Glycerol Acid, Heptacosane, Aluminum Starch Octylsuccinate, Benzyl Alcohol, Sorbitan Isostearate, VP-Eicosene Copolymer, Dimethicone, Polyacrylate-6 Copolymer, Tocopherol, Octyltrimellitate, Methylparaben, Propylparaben, Fragrance.

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

Questions or comments?
 Call 1-800-333-3344

Manufactured by:
 Western Family Products, Inc.
 201 1st Ave SW
 Portland, OR 97208 U.S.A.
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 www.westernfamily.com

MADE IN USA

WESTERN FAMILY BABY BROAD SPECTRUM SUNSCREEN SPF 50

avobenzone, homosalate, octocrylene, octisalate, oxybenzone lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:55312-007

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 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	7 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZHLLK470XV)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-007-57	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	07/02/2014	

Labeler - WESTERN FAMILY FOODS, INC. (192166072)

Revised: 7/2014

WESTERN FAMILY FOODS, INC.