

**MEIJER BABY SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion**  
**Meijer Distribution 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 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**), 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, 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

### **Principle Display Panel**



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<b>Active Ingredients</b> Avobenzone 3.0%, Homosalate 13.0%, Octisalate 5.0%, Octocrylene 7.0%, Oxybenzone 4.0%	<b>Purpose</b> 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. • 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.	
<b>Directions</b> • apply liberally 15 minutes before sun exposure • reapply: after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • <b>Sun Protection Measures.</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. - 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, 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.	
<b>Other information</b> • protect this product from excessive heat and direct sun	
Made in USA	
	
<b>DIST. BY MEIJER DISTRIBUTION, INC.</b> 2929 WALKER AVE NW GRAND RAPIDS, MI 49544 www.meijer.com	

## MEIJER BABY SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41250-003
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 mL in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mL in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 mL in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ0O6294)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-003-57	295 mL in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2012	

**Labeler** - Meijer Distribution Inc (006959555)

Revised: 1/2012

Meijer Distribution Inc