MEIJER SPF 15 - 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.

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

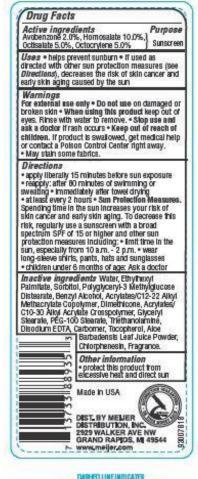
• protect this product from excessive heat and direct sun

Principal Display Panel

meijer
Sunscreen lotion
moisturizing
dermatologist tested
15
Broad Spectrum SPF 15
Water Resistant
(80 Minutes)
10 FL. OZ. (295 mL)



MEIJER 10 oz.
FRONT & BACK : CLEAR N
BROWN BACKGROUND
PRINT ALL OVER WHIT
DIE LINE DOES



DASHED LINEINDICATES
PRINT AREA (VISTH IN FROM DIELING)

BACK: CLEAR MATTE DIGITAL LABEL BACK COPY & SEAL: WHITE UPC: WHITE BOX BLACK BARS

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avobenzone, homosalate, octisalate, octocrylene lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-042	
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: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 g		
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	5 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ETHYLHEXYL PALMITATE (UNII: 2865993309)		
SORBITOL (UNII: 506T60A25R)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
PEG-100 STEARATE (UNII: YD0 1N1999R)		
TROLAMINE (UNII: 903K93S3TK)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
TOCOPHEROL (UNII: R0 ZB2556 P8)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
CHLO RPHENES IN (UNII: 1670 DAL4SZ)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:41250-042-57	286 g in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	07/17/2013		

Labeler - Meijer Distribution Inc (006959555)

Revised: 7/2013 Meijer Distribution Inc