SUNSCREEN SPF 15- avobenzone 2% homosalate 10% octisalate 5% octocrylene 5% lotion Meijer

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

2% Avobenzone

10% Homosalate

5% Octisalate

5% Octocrylene

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 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.

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: Ask a doctor

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Benzyl Alcohol, Carbomer, Cetyl Phosphate, Chlorphenesin, Dimethicone, Disodium EDTA, Ethylhexyl Palmitate, Fragrance, Polyamide-8, Sorbitol, Tocopherol, Triethanodamine, Water

Other Information

- protect this product from excessive heat and direct sun
- may stain fabrics



Di	ug	Fa	cts

Active ingredients	Purpose
Avobenzone 2%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 5%	Sunscreen

Uses • helps prevent sunburn • higher SPF gives more sunburn protection • retains SPF after 80 minutes of activity in the water or sweating • provides moderate protection against sunburn

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

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.

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: Ask
a doctor

Other information • protect this product from excessive heat and direct sun. • may stain fabrics.

Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Extract, Benzyl Alcohol, Carbomer, Cetyl Phosphate, Chlorphenesin, Dimethicone, Disodium EDTA, Ettylhexyl Palmitate, Fragrance, Polyamide-8, Sorbitol, Tocopherol, Triethanolamine, Water.

Questions? 866-483-2846

DIST. BY MEIJER DISTRIBUTION, INC. 2929 WALKER, NW, GRAND RAPIDS, MI 49544



SUNSCREEN SPF 15

avobenzone 2% homosalate 10% octisalate 5% octocrylene 5% lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC
--

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Active ingredicite Molecty				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 mL		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL		
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809 Y72KV36)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CETYL PHO SPHATE (UNII: VT07D6 X67O)	
CHLORPHENESIN (UNII: 1670 DAL4SZ)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
LP-20 (UNII: 3RQ1LHQ82N)	
SORBITOL (UNII: 506T60A25R)	
.ALPHATO COPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

	Packa	ging			
ı	# It	em Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:	41250-996-10	295 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/19 /20 17	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 1/19/20 17	

Labeler - Meijer (006959555)

Registrant - Producuct Quest Mfg, LLC (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg, LLC		927768135	manufacture(41250-996), label(41250-996)	

Revised: 7/2018 Meijer