SUNSCREEN SPF 50- avobenzone 3% homosalate 13% octisalate 5% octocrylene 7% oxybenzone 4% lotion

Premier Value

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

3% Avobenzone

13% Homosalate

5% Octisalate

7% Octocrylene

4% Oxybenzone

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

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

Other Information

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

Questions? 866-483-2846



Sunscreen Lotion

BROAD SPECTRUM SPF 50

water resistant (80 minutes)

UVA/UVB protection

hypoallergenic

50

NET WT 8 OZ (227 g)



Drug Facts

	10-76
Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 13%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 7%	Sunscreen
Oxybenzone 4%	Sunscreen

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

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

Questions? 866-483-2846

DISTRIBUTED BY CHAIN DRUG CONSORTIUM 3301 NW BOCA RATON BLVD SUITE 101, BOCA RATON, FL 33431



If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.



SUNSCREEN SPF 50

avobenzone 3% homosalate 13% octisalate 5% octocrylene 7% oxybenzone 4% lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68016-270

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: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 g
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	4 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19 PJ 0 O 6 2 9 4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470 XV)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TROLAMINE (UNII: 9O3K93S3TK)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:68016-270-06	227 g in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2012	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/26/2012	

Labeler - Premier Value (101668460)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg, LLC		927768135	manufacture(68016-270), label(68016-270)	

Revised: 8/2018 Premier Value