BROAD SPECTRUM SPF 50 DAYLOGIC- avobenzone 3% homosalate 13% octisalate 5% octocrylene 7% oxybenzone 4% lotion Rite Aid

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 sunburns

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



Drug Facts Active ingredients Purpose Avobenzone 3% Sunscreen Homosalate 13%. Sunscreen Octisalate 5%. Sunscreen Octocrylene 7% Sunscreen Oxybenzone 4%. Sunscreen Uses • helps prevent 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. Inactive ingredients Water, Sorbitol, Aluminum Starch Octenylsuccinate, VP/Eicosene Copolymer, Stearic Acid, Tocopherol, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Polyglyceryl-3 Distearate, Sorbitan 0 Isostearate, Triethanolamine, Methylparaben, Propylparaben, Fragrance. DISTRIBUTED BY: RITE AID 30 HUNTER LANE CAMP HILL, PA 17011 MADE IN THE USA WITH DOMESTIC AND FOREIGN COMPONENTS

look great

100% GUARANTEE

BROAD SPECTRUM SPF 50 DAYLOGIC

Route of Administration

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

TOPICAL

Product Information Product Type HUMAN OTC DRUG NDC:11822-7791 Item Code (Source)

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	7 g in 100 mL
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	4 g in 100 mL

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: A2I8 C7HI9 T)	
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)	
WATER (UNII: 059QF0KO0R)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:11822-7791-6	236 mL in 1 TUBE; Type 0: Not a Combination Product	09/26/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/26/2016	

Labeler - Rite Aid (014578892)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg, LLC		927768135	manufacture(11822-7791), label(11822-7791)	

Revised: 5/2018 Rite Aid