

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

Top Care

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



**MOISTURIZING
sunscreen
lotion**

**water resistant
(80 minutes)**

UVA/UVB protection

**Broad Spectrum
SPF 50**

***COMPARE TO THE ACTIVE
INGREDIENTS IN COPPERTONE®**

8 FL OZ (237 mL)

Drug Facts

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Octisalate 5%	Sunscreen
Octocrylene 7%	Sunscreen
Oxybenzone 4%	Sunscreen

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 www.topcarebrand.com



This Top Care® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

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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:36800-714
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 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	7 g in 100 mL

OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	4 g in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	
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:36800-714-06	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/23/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/23/2016	

Labeler - Top Care (006935977)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	manufacture(36800-714) , label(36800-714)