

**TANNING SUNSCREEN SPF 15- avobenzone 2% homosalate 10% octisalate 5% octocrylene
5% 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.

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 Barbadosensis Leaf Juice, Benzyl Alcohol, Carbomer, Cetyl Phosphate, Chlorphenesin, Dimethicone, Disodium EDTA, Ethylhexyl Palmitate, Fragrance, Polyamide-8, Sorbitol, Tocopherol, Triethanolamine, Water

Other Information

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



The image shows the packaging for TopCare Tanning Sunscreen Lotion. The main part of the box is red with a large sun graphic at the top left. The text on the box includes: 'TopCare. TANNING SUNSCREEN LOTION', 'water resistant (80 minutes)', 'UVA/UVB protection', 'Broad Spectrum SPF 15', and '8 FL OZ (237 mL)'. A blue banner at the bottom left contains the text '*COMPARE TO THE ACTIVE INGREDIENTS IN COPPERTONE®'. On the right side of the box, there is a white panel with black text containing 'Drug Facts', 'Uses', 'Warnings', 'Directions', 'Other information', and 'Inactive ingredients'. At the bottom right, there is a barcode with the number '0 36800 63301 8' and a 'QUALITY GUARANTEED' seal. Below the seal, it says 'This Top Care® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.' At the very bottom right, it states '*THIS PRODUCT IS NOT MANUFACTURED OR DISTRIBUTED BY BAYER CONSUMER CARE, LLC., DISTRIBUTOR OF COPPERTONE®'.

TopCare.
TANNING
SUNSCREEN LOTION

water resistant
(80 minutes)

UVA/UVB protection

Broad Spectrum
SPF 15

*COMPARE TO THE ACTIVE
INGREDIENTS IN COPPERTONE®

8 FL OZ (237 mL)

Drug Facts

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Avobenzone 2%.....	Sunscreen
Homosalate 10%.....	Sunscreen
Octisalate 5%.....	Sunscreen
Octocrylene 5%.....	Sunscreen

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ELK GROVE VILLAGE, IL 60007
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QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com

QUALITY GUARANTEED

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0 36800 63301 8

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-885
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 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
LP-20 (UNII: 3RQ1LHQ82N)	
SORBITOL (UNII: 506T60A25R)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-885-06	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(36800-885) , label(36800-885)

Revised: 6/2018

Top Care