

SPORT SUNSCREEN SPF 50 TOPCARE- avobenzone 3.00% homosalate 10.00% octisalate 5.00% octocrylene 5.00% spray

Topco

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

Purpose

Avobenzone - 3.00%
Homosalate - 10.00%
Octisalate - 5.00%
Octocrylene - 5.00%

Sunscreen

- 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

spray liberally and spread evenly by hand 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/Dimethicone Copolymer
Acrylates/Octylacrylamide Copolymer
Alcohol Denat.
Aloe Barbadensis Leaf Extract
Cyclopentasiloxane

Dimethicone
 Fragrance
 Polyester-8
 PPG-5-Ceteth-20
 Tocopheryl Acetate
 Trisiloxane

TopCare[®]
SPORT
 sunscreen spray

water resistant
 (80 minutes)
 UVA/UVB protection

Broad Spectrum
SPF 50

*COMPARE TO THE ACTIVE
 INGREDIENTS IN BANANA BOAT[®]

NET WT 6 OZ (170 g)

Drug Facts		Drug Facts (continued)
Active ingredients	Purpose	Other information
Avobenzone 3%.....Sunscreen Homosalate 10%.....Sunscreen Octisalate 5%.....Sunscreen Octocrylene 5%.....Sunscreen		• protect this product from excessive heat and direct sun. • may stain fabrics.
Uses • helps prevent sunburn • higher SPF gives more sunburn protection • If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by sun.		Inactive ingredients Acrylates/Dimethicone Copolymer, Acrylates/Octylacrylamide Copolymer, Alcohol Denat., Aloe Barbodensis Leaf Extract, Cyclopentasiloxane, Dimethicone, Fragrance, Polyester-8, PPG-5-Ceteth-20, Tocopheryl Acetate, Trisiloxane.
Warnings For external use only Flammable: Do not use near heat, flame, or while smoking. Do not use on damaged or broken skin When using this product • Keep out of eyes. Rinse eyes with water to remove. • Keep away from face to avoid breathing it • Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F. 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 • spray liberally and spread evenly by hand 15 minutes before sun exposure • reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • hold container 4 to 6 inches from the skin to apply • do not spray directly into face. Spray on hands then apply to face. • do not apply in windy conditions • use in a well-ventilated area 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		

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

SPORT SUNSCREEN SPF 50 TOPCARE

avobenzone 3.00% homosalate 10.00% octisalate 5.00% octocrylene 5.00% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-868
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	10 g in 100 g
Octisalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	5 g in 100 g
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ALOE (UNII: V5VD430YW9)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
Dimethicone (UNII: 92RU3N3Y1O)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
PPG-5-Ceteth-20 (UNII: 4AAN25P8P4)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
Trisiloxane (UNII: 9G1ZW13R0G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-868-05	170 g in 1 CAN; Type 0: Not a Combination Product	02/29/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/29/2016	

Labeler - Topco (006935977)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(36800-868) , label(36800-868)

Revised: 5/2018

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