SPORT SUNSCREEN SPF 30 TOPCARE- avobenzone 2.00% homosalate 7.00% 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 - 2.00% Homosalate - 7.00% Octocrylene - 5.00%

Sunscreen

- helps prevent sunburn
- if used as directed with other sun protection messures (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



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avobenzone 2.00% homosalate 7.00% octocrylene 5.00% spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-869
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 g	

Homo	osalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	7 g in 100 g
Octo	crylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	5 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
ALOE (UNII: V5VD430 YW9)		
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)		
Dimethicone (UNII: 92RU3N3Y1O)		
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296U138P)		
PPG-5-Ceteth-20 (UNII: 4AAN25P8P4)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8 X80 D2L0)		
Trisiloxane (UNII: 9G1ZW13R0G)		

l	Packaging			
# Item Code Package Description		Marketing Start Date	Marketing End Date	
ı	1 NDC:36800-869-05	170 g in 1 CAN; 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 - TopCo (006935977)

Registrant - Product Quest Mfg (927768135)

Establishment			
Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(36800-869), label(36800-869)

Revised: 5/2018 TopCo