# SPORT SUNSCREEN SPF 70- avobenzone 3% homosalate 15% octisalate 5% octocrylene 10% oxybenzone 6% spray TopCare

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.

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## **Drug Facts**

Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 15%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 10%	Sunscreen
Oxybenzone 6%	Sunscreen

**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.

## 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

**Other information** • protect this product from excessive heat and direct sun. • may stain fabrics.

## **Inactive Ingredients:**

Acrylates/Octylacrylamide Copolymer Alcohol Denat. Caprylic/Capric Triglyceride Diethylhexyl Syringylidenemalonate Fragrance Glycerin



avobenzone 3% homosalate 15% octisalate 5% octocrylene 10% oxybenzone 6% spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-728
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)	Ho mo salate	15 g in 100 g	
Octisalate (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	Octisalate	5 g in 100 g	
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	10 g in 100 g	
Oxybenzone (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	Oxybenzone	6 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
ALCOHOL (UNII: 3K9958V90M)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
Diethylhexyl Syringylidenemalonate (UNII: 3V5U97P248)			
Glycerin (UNII: PDC6 A3C0 OX)			

I	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:36800-728-05	170 g in 1 CAN; Type 0: Not a Combination Product	02/23/2016	
2	NDC:36800-728-06	227 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** - TopCare (006935977)

# **Registrant -** Product Quest Mfg (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg		927768135	manufacture(36800-728, 36800-728)	

Revised: 7/2018 TopCare