SPORT SUNSCREEN SPF 30- avobenzone 3% homosalate 10% octisalate 5% octocrylene 2% oxybenzone 4% spray Care One

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	
Avobenzone 3.0%	Sunscreen
Homosalate 10.0%	Sunscreen
Octisalate 5.0%	Sunscreen
Octocrylene 2.0%	Sunscreen
Oxybenzone 4.0%	Sunscreen

Uses • helps prevent sunburn • higher SPF gives more sunburn protection • retains SPF after 80 minutes of activity in the water or sweating • provides high protection against sunburn

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

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

Inactive ingredients

Acrylates/Octylacrylamide Copolymer, Alcohol Denat., Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Fragrance, Glycerin, Retinyl Palmitate, Stearoxytrimethylsilane, Tocopherol.



Drug Facts		
Active ingredient	Purpose	
Avobenzone 3%	Sunscreen	
Homosalate 10%		
Octisalate 5%	Sunscreen	
Octocrylene 2%	Sunscreen	
Oxybenzone 4%	Sunscreen	

Uses • helps prevent sunburn • higher SPF gives more sunburn protection
• retains SPF after 80 minutes of activity in the water or sweating • provides high protection against sunburn

Warnings

Flammable: Do not use near heat, flame, or while smoking

For external use only

Do not use on damaged or broken skin.

When using this product keep away from face to avoid breathing it • 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.

Avoid spraying in eyes. • Contents under pressure. Do not puncture or incinerate. • Do not store at temperature above 120°F.

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 be cause. • Do not apply in windy conditions • use in a well-ventilated area • Children under 6 months of age: ask a doctor. • 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 value 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-sleeved shirts, pants, hats, and sunglasses.

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

Inactive ingredients Acrylates/Octylacrylamide Copolymer, Alcohol Denat., Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Fragrance, Glycerin, Retinyl Palmitate, Stearoxytrimethylsilane, Tocopherol.

Questions? 1-877-846-9949

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SPORT SUNSCREEN SPF 30

avobenzone 3% homosalate 10% octisalate 5% octocrylene 2% oxybenzone 4% spray

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:41520-346

Route of Administration TOPICAL

Active Ingredient/Active Moiety **Ingredient Name Basis of Strength** Strength Avobenzone (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) 3 g in 100 g Avobenzone Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S) Ho mo sa la te 10 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 2 g in 100 g

Oxybenzone (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	Oxybenzone	4 g in 100 g
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Inactive Ingredients			
Ingredient Name	Strength		
ALCOHOL (UNII: 3K9958V90M)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
Diethylhexyl Syringylidenemalonate (UNII: 3V5U97P248)			
Glycerin (UNII: PDC6A3C0OX)			
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)			
Stearoxytrimethylsilane (UNII: 9862TW94B2)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			

Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:41520-346-05	170 g in 1 CAN; Type 0: Not a Combination Product	04/13/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/13/2018	

Labeler - Care One (809183973)

Registrant - Product Quest Mfg (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg		927768135	manufacture(41520-346), label(41520-346)	

Revised: 7/2018 Care One